UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON
AT TACOMA

IN RE CYTODYN STOCKHOLDER DERIVATIVE LITIGATION

Master File No.: 3:21-cv-05422-BHS

CONSOLIDATED VERIFIED STOCKHOLDER DERIVATIVE COMPLAINT

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Plaintiffs David Berndt, Christopher Lavin, and Billie Ray Hensley by and through their undersigned counsel, derivatively on behalf of Nominal Defendant CytoDyn, Inc. ("CytoDyn" or the "Company"), submit this Consolidated Verified Shareholder Derivative Complaint (the "Complaint"). Plaintiffs' allegations are based upon their personal knowledge as to themselves and their own acts, and upon information and belief, developed from the investigation and analysis by Plaintiffs' counsel, including a review of publicly available information, including filings by CytoDyn with the U.S. Securities and Exchange Commission ("SEC"), press releases, news reports, analyst reports, investor conference transcripts, publicly available filings in lawsuits, and matters of public record.

I. NATURE OF THE ACTION

1. This is a shareholder derivative action brought on behalf of and for the benefit of the Company, against certain of its officers and/or directors named as defendants herein seeking to remedy Defendants' (defined below) breaches of fiduciary duties, contribution for violations of Section 10(b) and 21(D) of the Securities Exchange Act of 1934 (the "Exchange Act"), and other wrongful conduct as alleged herein and that occurred from March 27, 2020 through the present (the "Relevant Period"). Defendants' actions have caused, and will continue to cause, substantial financial harm and other damages to the Company, including damages to its reputation and goodwill.

2. The Company, a late-stage biotechnology company, is focused on the development and commercialization of a *single* drug, leronlimab (a/k/a PRO 140 or Vyrologix). Throughout the Relevant Period, Defendants touted leronlimab as a potential treatment for patients suffering from various medical conditions, including HIV, COVID-19, and certain cancers.

3. During the Relevant Period, Defendants claimed that CytoDyn had filed a "complete" application seeking regulatory approval for leronlimab as a combinatory treatment for HIV. However, non-public information shows that they knowingly submitted an application that did not include several datasets that the U.S. Food and Drug Administration ("FDA") had

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already indicated was required—an email from CytoDyn's CEO to management stated that the application should be filed "even if we are short in no matter what portion of whatever it is that we are short" because the Company's stock price has declined substantially due to repeated delays with the submission. After just a "preliminary review," the FDA issued a "Refusal to File" Letter because CytoDyn's applications suffered "numerous omissions and inadequacies so severe as to render the application incomplete."

4. Rather than curing these deficiencies, Defendants pivoted to pushing leronlimab as a treatment for COVID-19. Over the course of two years, they caused CytoDyn to issue nearly 200 press releases that repeatedly touted leronlimab as a potential treatment for leronlimab. In the midst of news of purportedly positive clinical results, certain of Defendants sold nearly $31 million worth of their CytoDyn holdings, while in possession of material information that, in fact, leronlimab had not been shown to be effective in treating COVID-19.

5. Then, in March 2021, CytoDyn acknowledeged that clinical studies testing leronlimab as a treatment of COVID-19 did not meet its primary endpoint. This, however, was buried within releases masked by positive titles.

6. Defendants' conduct was so egregious that the FDA took the rare step of issuing a public statement on an unapproved drug. On May 17, 2021, the FDA stated that, based on clinical results collected thus far, "it has become clear that the data currently available do not support the clinical benefit of leronlimab for the treatment of COVID-19."

7. The foregoing revelations precipitated the filing of a securities class action in this District against CytoDyn and certain of the defendants named herein, captioned *Courter, et al. v. CytoDyn Inc., et al.*, Case No. 3:21-cv-05190-BHS (the "Securities Class Action").

8. At least half of the Company's current Board could not disinterestedly and independently respond to a litigation demand in connection with the misleading representations as alleged herein.

II. JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because Plaintiff's claims raise a federal question under Sections 10(b) and 21(D) of the Exchange Act.

10. This Court has supplemental jurisdiction over the remaining claims under 28 U.S.C. §1367.

11. This Court has jurisdiction over each defendant named herein because each defendant is either a corporation that conducts business in and maintains operations in this District or is an individual who has sufficient minimum contacts with this District to render the exercise of jurisdiction by the District courts permissible under traditional notions of fair play and substantial justice.

12. Venue is proper in this Court in accordance with 28 U.S.C. § 1391 because: (i) CytoDyn maintains its principal place of business in this District; (ii) one or more of the defendants either resides in or maintains executive offices in this District; (iii) a substantial portion of the transactions and wrongs complained of herein, including Defendants' primary participation in the wrongful acts detailed herein, in violation of fiduciary duties owed to CytoDyn, occurred in this District; and (iv) Defendants have received substantial compensation in this District by doing business here and engaging in numerous activities that had an effect in this District.

III. PARTIES

Plaintiffs

13. ***Plaintiff David Berndt*** ("Plaintiff Berndt") is a current owner of the Company's stock, purchasing his Company stock on June 24, 2020. Plaintiff Berndt has held the stock during the time of the continuous wrongful course of conduct alleged herein and continues to hold his CytoDyn stock. Plaintiff Berndt will fairly and adequately represent the interests of the stockholders in enforcing the rights of the Company.

14. ***Plaintiff Christopher Lavin*** ("Plaintiff Lavin") is a current owner of the Company's stock, purchasing his Company stock on August 20, 2020. Plaintiff Lavin has held

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the stock during the time of the continuous wrongful course of conduct alleged herein and continues to hold his CytoDyn stock. Plaintiff Lavin will fairly and adequately represent the interests of the stockholders in enforcing the rights of the Company.

15. ***Plaintiff Billie Ray Hensley*** ("Plaintiff Hensley") is a current owner of the Company's stock, purchasing his Company stock on September 12, 2008. Plaintiff Hensley has held the stock during the time of the continuous wrongful course of conduct alleged herein and continues to hold his CytoDyn stock. Plaintiff Hensley will fairly and adequately represent the interests of the stockholders in enforcing the rights of the Company.

Nominal Defendant

16. ***Nominal Defendant CytoDyn*** is a biotechnology company. Headquartered in Vancouver, Washington, and incorporated in Delaware, the Company is focused on the development and commercialization of a drug, leronlimab, which has long been promoted as a potential therapy for HIV patients.

Director Defendants

17. ***Defendant Scott A. Kelly, M.D.*** ("Kelly") was named Chairman of the Board in December 2018 and has served as a director since April 2017. Defendant Kelly was named to the non-executive position of Chief Science Officer of the Company in July 2019. He was also appointed Chief Medical Officer and Head of Business Development in April 2020.

18. ***Defendant Nader Z. Pourhassan, Ph.D.*** ("Pourhassan") joined the Company in 2008 as Chief Operating Officer and by September 2012, was appointed President and CEO. Defendant Pourhassan is also a director. He is named as a defendant in the Securities Class Action.

19. ***Defendant Jordan G. Naydenov*** ("Naydenov") has been a director of the Company since June 2009. He is a member of the Audit Committee.

20. ***Defendant Alan P. Timmins*** ("Timmins") served as a director of the Company from January 2020 to November 2021. He was Chair of the Audit Committee.

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21. ***Defendant Samir R. Patel, M.D.*** ("Patel") served as a director of the Company from April 2020 to November 2021.

22. Defendants Kelley, Pourhassan, Naydenov, Timmins and Patel are collectively referred to as the "Director Defendants."

Officer Defendant

23. ***Defendant Michael Mulholland*** ("Mulholland") is the Company's Chief Financial Officer ("CFO"). He is named as a defendant in the Securities Class Action.

24. The Director Defendants and Defendant Mulholland are herein referred to as "Defendants."

IV. SUBSTANTIVE ALLEGATIONS

A. Relevant Regulatory Framework

25. The Company, a late-stage biotechnology company, is focused on the development and commercialization of a *single* drug, leronlimab (a/k/a PRO 140 or Vyrologix). Throughout the Relevant Period, Defendants touted leronlimab as a potential treatment for patients suffering from various medical conditions, including HIV, COVID-19, and certain cancers.

26. According to the Company, leronlimab is "a monoclonal antibody C—C chemokine receptor type 5 ('CCR5') receptor antagonist. The target of leronlimab is the immunologic receptor CCR5…a protein located on the surface of various cells including white blood cells and cancer cells. On white blood cells, it serves as a receptor for chemical attractants called chemokines."

27. Chemokines are a family of chemoattractant cytokines (small proteins secreted by cells that influence the immune system) which play a vital role in cell migration through venules from blood into tissue and vice versa, and in the induction of cell movement in response to a chemical (chemokine) gradient by a process known as chemotaxis. "The CCR5 receptor has been identified as a target in HIV, GvHD (graft-versus-host disease), NASH [(nonalcoholic steatohepatitis)], cancer metastasis, transplantation medicine, multiple sclerosis, traumatic brain

injury, stroke recovery, and a variety of inflammatory conditions, including potentially COVID-19."

28. Leronlimab is a type of drug known as a "biologic," meaning it is derived from living material as opposed to synthesized in a lab. According to the FDA:

> [b]iological products, like other drugs, are used for the treatment, prevention or cure of disease in humans. In contrast to chemically synthesized small molecular weight drugs, which have a well-defined structure and can be thoroughly characterized, biological products are generally derived from living material—human, animal, or microorganism—are complex in structure, and thus are usually not fully characterized.

29. And "Section 351 of the *Public Health Service (PHS) Act* defines a biological product as a 'virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings.'" (Alteration in original).

1. BLA and Investigational New Drug Application

30. The FDA typically requires an Investigational New Drug ("IND") Application for any clinical investigation involving administration of a drug to humans. Following initial laboratory and animal testing that show that investigational use in humans is reasonably safe, biological products like leronlimab can be studied in clinical trials in humans under an IND application. Upon receipt of an IND application, the FDA will notify the applicant of the date it received the application, and, within a set period of time, whether the IND applicant can begin the proposed clinical research stage.

31. According to the FDA, there are three phases that apply to the pre-marketing clinical research stage. During Phase 1, researchers test an experimental drug or treatment in a small group of people for the first time and the researchers evaluate the drug's safety and determine a safe dosage range. The FDA recommends 20 to 100 healthy volunteers or people with the disease/condition for study participants and a study length of several months.

32. During Phase 2, the experimental drug or treatment is given to a larger group of people to see if it is effective and to evaluate its side effects. The FDA recommends several

hundred people with the disease/condition for study participants and a study length of several months to two years.

33. During Phase 3, researchers give the experimental drug or treatment to large groups of people. Researchers confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely. The FDA recommends 300 to 3,000 volunteers who have the relevant disease/condition for study participants and a study length of one to four years.

34. If the data generated by at least two Phase 1-3 trials demonstrate that the product is safe and effective for its intended use, the data are submitted to the FDA as part of a marketing application. Whereas a New Drug Application ("NDA") is used for drugs subject to the drug approval provisions of the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), a Biologics License Application ("BLA") is required for biological products subject to licensure under the Public Health Services Act, such as leronlimab. FDA approval to market a biologic is granted by issuance of a biologics license. The ultimate issuance of a biologics license is a determination that the product, the manufacturing process, and the manufacturing facilities meet applicable requirements to ensure the continued safety, purity and potency of the product.

35. In accordance with these and related regulations, it was necessary for CytoDyn to submit a BLA to the FDA to obtain a biologics license in order to market and sell leronlimab in the United States. FDA Form 356h specifies the requirements for a BLA: (1) applicant information; (2) product/manufacturing information; (3) pre-clinical studies; (4) clinical studies; and (5) labeling. The FDA specifies in detail the information that an applicant must submit in a BLA. A BLA applicant's Responsible Official must also acknowledge that "[t]he data and information in this submission have been reviewed and, to the best of my knowledge, are certified to be true and accurate."

36. Prior to submitting a BLA, an applicant is encouraged to discuss the planned content of the application with the appropriate review division of the FDA at a pre-BLA meeting. According to the FDA, "the pre-[]BLA meeting should be held sufficiently in advance of the

planned submission of the application to allow for meaningful response to FDA feedback . . .” and “[t]he FDA and the applicant will agree on the content of a complete application for the proposed indication(s) at the pre-submission meeting.” According to the FDA, ***“[m]ajor components of the application (e.g., the complete study report of a Phase 3 clinical trial or the full study report of required long-term safety data) are expected to be submitted with the original application and are not subject to agreement for late submission***.”[1]

37. Moreover, the FDA makes clear that “[a]pplications are expected to be complete, as agreed between the FDA review team and the applicant at the pre-NDA/BLA meeting, at the time of original submission of the application” and incomplete applications “will be subject to a ***Refuse-to-File decision***.”

38. At any time when submitting a BLA, a drug company can seek “Fast Track” designation. According to the FDA, “Fast track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need.” Such a designation “must be requested by the drug company . . . any time during the drug development process. [The] FDA will review the request and make a decision within sixty days based on whether the drug fills an unmet medical need in a serious condition.”

39. If it receives a Fast Track designation for a proposed drug, an applicant is eligible for some or all of: (1) more frequent meetings with the FDA to discuss the drug’s development plan and ensure collection of appropriate data needed to support drug approval; (2) more frequent written communication from the FDA about such things as the design of the proposed clinical trials and use of biomarkers; (3) eligibility for “Accelerated Approval and Priority Review,” if certain criteria are met; and (4) “Rolling Review,” which means that the applicant can submit sections of its BLA for review by the FDA, rather than waiting until every section of the BLA is completed before the entire application can be reviewed. The specific parameters of a Rolling Review must be determined with the FDA.

[1] Unless otherwise stated, all emphasis in bold and italics hereinafter is added.

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40. Typically, the FDA only accepts the submission of one complete section of a BLA, e.g., the entire clinical section; however, the FDA may, on occasion, "in its discretion accept less than a complete section. . ." If an applicant submits its BLA in sections, each section "should be submitted for review in a form adequate to have been included in a complete BLA . . . submission." Notably, "[d]rafts should not be included in a submission; if final reports need to be updated, the applicant should submit a formal amendment to the BLA . . . with the revised information." According to the FDA, "[a]t the pre-BLA . . . meeting, the [FDA] and the [applicant] should work together to clearly define the parameters of accepting an incomplete section and to determine whether FDA could conduct a meaningful review of the submission before receiving the missing information."

41. After the BLA is submitted, the FDA conducts a review, generally within sixty days, to determine whether the BLA submission is complete. The result of the FDA's review is either a filing letter or, in rare instances, a Refuse to File ("RTF") notification. If the BLA submission is acceptable for review, the Prescription Drug User Fee Act ("PDUFA") indicates that the FDA intends to review 90% of standard BLA submissions within ten months of the sixty-day filing date and 90% of priority BLA submissions within six months of the sixty-day filing date. The date at the end of the review period is generally referred to as the PDUFA date.

42. In sum, in order to obtain a biologics license for leronlimab, CytoDyn needed to adhere to the foregoing process and timely submit a BLA containing the necessary information to the FDA.

2. The FDA's Use of Emergency Use Authorizations (EUA) in Lieu of The BLA Process

43. In extraordinary circumstances, biotechnology or drug companies can seek to distribute a drug under a rarely used process called Emergency Use Authorization ("EUA"). Under Section 564 of the FD&C Act, when the Secretary of the United States Department of Health & Human Services ("HHS") declares that an emergency use authorization is appropriate, the FDA may authorize unapproved medical products or unapproved uses of approved medical

products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or other threats when certain criteria are met, including where there are no adequate, approved, and available alternatives.

44. According to the FDA, the EUA "authority allows FDA to help strengthen the nation's public health protections . . . infectious diseases, by facilitating the availability and use of medical countermeasures (MCMs) needed during public health emergencies." In the recent past, the FDA issued EUAs for Anthrax Vaccine Adsorbed, H1N1 (i.e., swine flu), Middle East Respiratory Syndrome Coronavirus (MERS-CoV), Ebola Virus, and Zika Virus.

45. On January 31, 2020, the Secretary of HHS issued a Determination that a Public Health Emergency Exists and declared: "As a result of confirmed cases of 2019 Novel Coronavirus (2019-nCoV) . . . a public health emergency exists and has existed since January 27, 2020, nationwide." On February 4, 2020, the Secretary of HHS issued another determination that "Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the FD&C Act." And on March 27, 2020, with an effective date of February 4, 2020, the Secretary of the HHS declared that the FDA Commissioner could issue EUA for drugs and biological products for emergency use under section 564 of the FD&C Act."

46. The FDA recommends that an EUA request contain safety and efficacy data for a product, among other categories of information. While clinical trials are not required for an EUA submission, they are recommended for otherwise unapproved products, such as leronlimab. Further, the FDA "encourages any [applicant] of a candidate product to have early discussions with FDA . . . about the nature and type of safety data that might be appropriate."

3. "Emergency" and Expanded Access/Compassionate Use

47. The FDA's "emergency use" exemption allows the use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and there is not sufficient time to obtain Institutional Review Board ("IRB") approval.

48. Separately, according to the FDA, expanded access, sometimes called "compassionate use," involves the use of an investigational new drug product outside of clinical

trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options.

49. This mechanism is primarily intended to give seriously ill patients access to experimental drugs or devices where no comparable or satisfactory alternative treatment is available. Although the test article applicant is expected to continue conventional clinical trials and pursue marketing approvals with due diligence, expanded access studies involve systematic use of experimental treatments, and, with very rare exceptions, require rigorous review and approval, including both IRB approval and FDA approval in the form of an IND Application (drug/biologic).

B. The Company Pins Its Hopes For A Marketable Product On Leronlimab

50. CytoDyn's financial success, e.g., earning any revenue, let alone profits, hinged on the Company's ability to obtain regulatory approval to market and sell leronlimab. Indeed, CytoDyn articulated various "Risks Related to Our Business." For example, in risk disclosures published on August 14, 2019, CytoDyn stated:

> We have not generated any revenue from product sales, licensing, or other potential sales to date. Since our inception, we have incurred operating losses in each year due to costs incurred in connection with research and development activities and general and administrative expenses associated with our operations. Our current drug candidate, leronlimab, is in the later stages of clinical trials and the filing of a BLA is underway. During the fiscal years ended May 31, 2019 and 2018, we incurred net losses of approximately $56.2 million and $50.1 million, respectively, and at May 31, 2019, we had an accumulated deficit of approximately $229.4 million and a stockholders' deficit of $8.9 million. We expect to incur losses for the foreseeable future as we continue development of, and seek regulatory approvals for, our drug candidate and commercialize any approved product usages. If our current drug candidate fails to gain regulatory approval, or if it or other candidates we own do not achieve approval and market acceptance, we will not be able to generate any revenue, or explore other opportunities to enhance stockholder value, such as through a sale. If we fail to generate revenue and eventually become and remain profitable, or if we are unable to fund our continuing losses, our shareholders could lose all or part of their investments.

51. Absent any revenues from its business, in the years preceding the COVID-19 pandemic, CytoDyn had been constrained to fund its operations through various alternative financing arrangements with less than reputable partners.

C. CytoDyn's Financials

52. The Company has not shown any revenue and it has incurred operating losses each fiscal year due to costs of research and development activities. From 2019 to 2020, the Company's losses nearly doubled from $56.2 million in 2019 to $124.4 million in 2020. The Company's annual net losses:

FY	Net Losses
2012	$7,474,224
2013	$9,568,301
2014	$12,431,413
2015	$25,088,070
2016	$25,703,612
2017	$25,763,801
2018	$50,149,681
2019	$56,186,660
2020	$124,403,402

53. The Company's deficit also increased from $229.4 million in 2019 to $354.7 million in 2020. In 2020, the Company's financials were so bad that the Company's auditor reported a "going concern" warning:

> Our auditors issued an opinion, which includes a going concern exception, in connection with the audit of our annual financial statements for the fiscal year ended May 31, 2020. A going concern exception to an audit opinion means that there is substantial doubt that we can continue as an ongoing business for the next 12 months. If we are unable to continue as a going concern, we might have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. In addition, the inclusion of an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern and our lack of cash resources may materially adversely affect our share price and our ability to raise new capital or to enter into critical contractual relations with third-parties. There is no assurance that we will be able to adequately fund our operations in the future.

D. The Company Needs to Convince the Market it Can Regulatory Approval to Market Leronlimab

54. The Company's long-term ability to survive turned on obtaining regulatory approval to market and sell leronlimab. Investors had no other reason to invest money in the Company. Defendants had represented that the Company's efforts to achieve such approval for a BLA for an HIV indication ("HIV BLA") were making substantial progress. On July 16, 2018,

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CytoDyn announced the results for its pivotal Phase 3 trial studying the use of leronlimab in a combination therapy to treat HIV.

55. In March 2019, the *Portland Business Journal* reported that Defendant Pourhassan stated that the Company "would file the full [BLA] application by the end of 2019 and would have revenue in 2020."

56. On August 5, 2019, the Company reported progress on the HIV BLA submission with the FDA when it stated that it was granted "a small business waiver of application fees by" the FDA for the forthcoming HIV BLA. Moreover, Defendants stated in an October 11, 2019 press release that the FDA agreed to provide the Company with a "Fast Track" designation for the HIV BLA.

57. Also, on November 21, 2019, in a press release the Company stated that it had "successfully completed a Phase 3 pivotal trial with leronlimab in combination with standard anti-retroviral therapies in HIV-infected treatment-experienced patients. CytoDyn plans to seek FDA approval for leronlimab in combination therapy and plans to complete the filing of a Biologics License Application (BLA) in 2019 for that indication."

58. On December 16, 2019, the FDA communicated specific data and information that the Company needed to include in the leronlimab BLA:

> We acknowledge that you have selected 700 mg as the to be marketed dose. Assessing whether the data from CD03 and CD02 support the 700 mg dose for the intended population and indication will be a review issue. With your BLA submission, you should submit an integrated assessment and detailed summary that supports your selected dose and incorporates virologic outcomes, safety data (including laboratory abnormalities), exposure related data (including population pharmacokinectics and exposure-response relationship analyses), receptior occupancy data (including both method validation report and bioanalytical report of clinical samples), and anti-idiotypic antibody data (including both method validation report and bioanalytical report of clinical samples). The integrated assessment should reflect data from the 3 doses evaluated in CD03 and for the 350 mg dose evaluated in HTE MDR patients in CD02.

59. The Company did not share this communication or guidance, nor other specific guidance it had previously received from the FDA, with the market until October 26, 2021.

60. On December 17, 2019, the Company issued a press release stating that it had "entered into a Commercialization and License Agreement (CLA) and a related Supply Agreement to commercialize leronlimab (PRO 140) in the U.S. for the treatment of HIV [with Vyera Pharmaceuticals, LLC]" and:

> Under the terms of the CLA, CytoDyn will maintain responsibility for the development and FDA approval of leronlimab for all HIV-related and other indications, while Vyera has been granted an exclusive license to market and distribute leronlimab in the U.S. for the treatment of HIV. In exchange for such exclusive license, Vyera has agreed to pay upfront and regulatory and sales-based milestone payments of up to $87.5 million, as well as a royalty of 50 percent on net sales. Vyera also agreed to make an investment in CytoDyn of $4 million in the form of registered CytoDyn common stock.

61. On January 13, 2020, after missing its stated goal to file the HIV BLA in 2019, the Company issued a press release that stated: "CytoDyn plans to seek FDA approval for leronlimab in combination therapy and plans to complete the filing of a [BLA] in the first quarter of 2020 for that indication." The Company issued identical statements in subsequent press releases from January through March 2020.

62. On January 21, 2020, the Company announced that [it] "has successfully completed a Phase 3 pivotal trial with leronlimab in combination with standard anti-retroviral therapies in HIV-infected treatment-experienced patients. CytoDyn plans to seek FDA approval for leronlimab in combination therapy and plans to complete the filing of a [BLA] in the first quarter of 2020 for that indication."

63. However, at the end of the first quarter of 2020, the Company pushed the submission target date again. On March 30, 2020, the Company stated that "CytoDyn plans to seek FDA approval for leronlimab in combination therapy and plans to complete the filing of a [HIV BLA] in April of 2020 for that indication." The Company issued identical statements in ten subsequent press releases over the following three weeks.

E. The Company Finally Submits BLA Despite Knowledge That It Lacks Required Data and Information

64. In an e-mail to the BLA project heads, Defendant Pourhassan demanded that the application be submitted regardless of the internally well-known gaps and data deficiencies it

contained. On April 14, 2020, Defendant Pourhassan sent an e-mail to Kush Dhody, Kazem Kazempour, and Nitya Ray (the Company's Chief Technology Officer):

> Dear Nitya and Kush:
>
> Today we have so far in 1 hour almost 20% drop in our stock price. Yesterday we had drop also after putting out great results about COVID-19 patients we are seeing these type of decline.
>
> This drop will be much deeper if we don't file our BLA as the message board now is getting bombarded by investors who are very frustrated with me and CytoDyn.
>
> ***Please file the BLA no later than next week Wednesday, even if we are short in no matter what portion of whatever it is that we are short***.
>
> Dear Nitya: Please communicate with Kush about how much time they need to prepare the CMC[2] portion after you send it to them. Kush told me yesterday he needs one week if so, they need the CMC package tomorrow to make the next week's Wednesday deadline. Please talk to Kush to see if there is any way they could take 1-2 days to prepare the CMC portion for final filling as you and I discussed yesterday.
>
> Dear Kush: The COVID-19 is no longer CytoDyn's top priority as if the stock continues its drift then financially we will have problems financing itself. ***THE MOST IMPORTANT thing now is BLA. Please focus on that urgently only***.

65. Defendant Pourhassan's April 14, 2020 e-mail only became public in October 26, 2021, in a lawsuit entitled *CytoDyn, Inc. v. Amarex Clinical Research, LLC, et al.*, No. 21-cv-02533 (D. Md. Oct. 4, 2021).

66. Despite a plethora of deficiencies in the submission package about which Defendants knew but did not disclose to market, Defendants caused the Company to submit the HIV BLA to the FDA in late April 2020.

67. On April 27, 2020, the Company issued a press release entitled *CytoDyn Submits Completed Biologics License Application (BLA) to the FDA for Leronlimab as a Combination Therapy for Highly Treatment Experienced HIV Patients*. It was in that press release that Defendant Pourhassan stated:

> With the BLA filing for a combination therapy now complete, we are continuing our efforts on commercialization-readiness, as well as advancing leronlimab in

[2] "CMC" refers to the "Chemistry Section: (A) Chemistry, manufacturing, and controls information (*e.g.*, 21 CFR 314.50(d)(1); 21 CFR 601.2)" requested in connection with a BLA.

> the other important therapeutic areas of COVID-19, cancer and immunology. ***The BLA filing is a monumental achievement for our Company***. . .

68. Also, on April 27, 2020, during a Company conference call with investors, Defendant Pourhassan stated:

> [H]ave some exciting news for the use of leronlimab in treating patients infected with COVID-19. . .
>
> ***
>
> The first update is the BLA submission, which is a historical achievement for CytoDyn.
>
> As everyone knows, the BLA timeline was pushed back constantly. These push-backs were all due to CytoDyn's success. The first success is with a higher dose of leronlimab in monotherapy. Then it got pushed back because of the success of leronlimab application in coronavirus and overwhelming interest from hospitals and patients to get leronlimab, which led to initiation of two new clinical trials, which takes a tremendous amount of work from our CRO and our CytoDyn team.
>
> Then it got pushed back because of the coronavirus shutdown of the lab side, and even the manufacturing of leronlimab that shorted [out] the availability of our stability data from AGC.
>
> ***
>
> Our success with cancer also contributed to our delay of the BLA.
>
> ***
>
> The good news is, CytoDyn just filed the full BLA last night without slowing down our cancer programs, without slowing down our impressive work in coronavirus, and without blinking on the tremendous financial pressure from everywhere.
>
> ***
>
> Congratulations to Am[a]rex for not letting down all of our shareholders and many patients in great need of leronlimab. Special thanks goes to Dr. [Kush Dhody] and the main person at Am[a]rex, their CEO, Dr. [Kazem Kazempour], and to CytoDyn's team, especially our Chief Technology Officer, Dr. Nitya Ray who took the CMC shattered pieces and successfully put it back together in an artistic fashion; and in doing so, he also finalized a superb deal for CytoDyn with Samsung Biologics. ***So in short, ladies and gentlemen, the BLA is submitted.***
>
> ***
>
> It is very important, as CytoDyn's story gets unfolded, that shareholders realize the value that one man has brought to us, and he is CytoDyn's chairman of the board and chief medical officer, Dr. Scott Kelly. As the CEO of CytoDyn, I went through a lot of challenges in the last eight years, and without Dr. Kelly, most of our victories would not been [sic] possible. ***The BLA got filed.***

(Second set of brackets in original.)

69. On April 30, 2020, in a Company press release, the Company affirmed: "CytoDyn completed the filing of its BLA in April 2020 to seek FDA approval for leronlimab as a combination therapy for highly treatment experienced HIV patients."

70. On April 30, 2020, May 1, 2020 and May 4, 2020 after the Company announcement mentioned below, Defendant Pourhassan reaped over $15 million in insider sales proceeds.

71. On May 1, 2020, Defendant Kelly reaped over $3.9 million in insider sales proceeds.

72. Defendants Pourhassan and Kelly were motivated in whole, or in part, to make these sales while in possession of adverse material nonpublic information regarding the deficient BLA for leronlimab.

73. Only a few days after Defendants Pourhassan's and Kelly's combined $16.3 million in sales, the Company issued a press release regarding its request for compassionate use clearance for leronlimab to treat COVID-19, whereby the Company stated: "[w]e would like to provide an update that the Biologics License Application (BLA) for Leronlimab as a Combination Therapy for Highly Treatment Experienced HIV Patients will be considered completed after the clinical datasets are submitted on May 11, 2020." This was the first disclosure to inform the market of shortcomings with the HIV BLA submission. As a result, the Company's stock price fell approximately 13% on the news on May 4, 2020.

74. On May 6, 2020 and May 7, 2020, the Company issued press releases repeating the same information, and on May 8, 2020, the Company issued a press release that stated, "[t]he BLA will not be considered completed until the Company submits to the FDA clinical datasets required to address FDA comments it received in March 2020, as described in the Company's press releases on May 4 and May 6, 2020. CytoDyn expects to submit these clinical datasets on May 11, 2020."

75. On May 15, 2020, the Company issued a press release stating: "[t]he Company filed its BLA for Leronlimab as a Combination Therapy for Highly Treatment Experienced HIV Patients with the FDA on April 27, 2020, and submitted additional FDA requested clinical datasets on May 11, 2020."

76. Defendants then extolled the so-called progress of the application and positive feedback the Company received from the FDA. For instance, during a June 5, 2020, Proactive Investors interview, Defendant Pourhassan reported that CytoDyn was communicating with the FDA regarding the BLA and "had the discussion with the [FDA] just a few days ago, very, very positive discussions."

1. The FDA Rejects the Company's HIV BLA Submission in a Non-Public RTF Letter

77. On July 8, 2020, the FDA informed the Company in a non-public communication that it had rejected the Company's HIV BLA submission, and provided the Company with an RTF notification:

> After a ***preliminary review***, we find your application does not contain all pertinent information and data needed to complete a substantive review. Therefore, we are refusing to file this application under 21 CFR 601.2(a).
>
> The application has numerous omissions and inadequacies ***so severe*** as to render the application incomplete and also introduces significant impediments to a prompt and meaningful review because there is the need for substantial amounts of additional data and analyses along with corrections in datasets.
>
> We are refusing to file this application for the reasons identified below. Section I provides a high-level summary of the deficiencies and Section II provides a detailed description of each deficiency and the information needed to resolve the deficiency.

78. The substance of the RTF Letter was not disclosed to the market at that time. The RTF Letter was not made public until October 26, 2021, in *CytoDyn, Inc. v. Amarex Clinical Research, LLC, et al.*, No. 21-cv-02533 (D. Md. Oct. 4, 2021).

79. Among other points, the FDA RTF Letter noted:

> The BLA ***does not include critical information and analyses*** needed to permit substantive clinical, statistical, clinical virology and clinical pharmacology review of your proposed dose. In many cases, these issues are deficiencies that were clearly communicated to you before submission of the application (*see* Section II

for specific details). These deficiencies require resolution before a meaningful review can occur.

80. The FDA RTF Letter also noted:

> There is an absence of important variables (*e.g.*, time to virologic failure at the assigned dose) and analysis group flags in the analysis files containing the primary efficacy data needed for substantive clinical, statistical, clinical virology and clinical pharmacology review of your product. Additionally, the datasets have numerous instances of missing data and the files are not adequately defined or properly indexed.

81. The FDA RTF Letter further noted:

> Assessing the safety and effectiveness in subpopulations (sex, age, race, and ethnicity) is an integral part of the BLA review. Your BLA did not include analyses of subpopulations with regard to effectiveness; the Summary of Clinical Efficacy, the CD02 CSR, and the CD03 CSR did not include these analyses and the ISE was omitted from the submission. While the ISS and Summary of Clinical Safety included sections with relevant titles such as "Adverse Events by Age" and "Adverse Events by Gender", the content of these sections was largely line-listings without substantive assessments addressing whether age or sex appeared to have impacted safety outcomes in your clinical development program. Neither the ISS nor the Summary of Clinical Safety includes analyses of safety by race or ethnicity.

82. The FDA RTF Letter also noted that "[n]o data from studies conducted with the drug in the device were included in the submission, and no information is included on the manufacturer of the syringe and needles."

83. The FDA RTF Letter further explained that, on December 16, 2019, it had expressly told the Company:

> We acknowledge that you have selected 700 mg as the to be marketed dose. Assessing whether the data from CD03 and CD02 support the 700 mg dose for the intended population and indication will be a review issue. With your BLA submission, you should submit an integrated assessment and detailed summary that supports your selected dose and incorporates virologic outcomes, safety data (including laboratory abnormalities), exposure related data (including population pharmacokinectics and exposure-response relationship analyses), receptior occupancy data (including both method validation report and bioanalytical report of clinical samples), and anti-idiotypic antibody data (including both method validation report and bioanalytical report of clinical samples). The integrated assessment should reflect data from the 3 doses evaluated in CD03 and for the 350 mg dose evaluated in HTE MDR patients in CD02.

84. The FDA RTF Letter further stated:

> Despite the specific advice above, which echoed the advice we provided you on January 22, 2019, following our presentation of the revised BLA submission plan

> to the CDER's Medical Policy and Program Review Council (MPPRC), the BLA includes only a 2-page "Rationale for Dose Section" that is identical to the rationale you provided with the proposed CD08 trial, which we told you in our June 3, 2019, correspondence was insufficient.
>
> ***Your application does not include the information and analyses needed to permit FDA reviewers (clinical, statistical, clinical virology and clinical pharmacology) to perform a substantive review of the proposed dose***. The application ***is missing*** an integrated assessment that incorporates detailed summaries reflecting data from the participants randomized to receive 350 mg, 525mg, and 700mg in CD03 and for the 350 mg dose evaluated in HTE MDR patients in CD02. Furthermore, your application does not include multiple reports that are needed to permit a substantive review.

85. The FDA RTF Letter also provided detailed descriptions concerning the deficiencies in the Company's BLA.

2. The Company Tries To Deflect The Substance Of The RTF Letter

86. On July 13, 2020, the Company disclosed that it had received the RTF Letter from the FDA for the HIV BLA. However, Defendants concealed that they had submitted (and resubmitted) the HIV BLA even though they knew it lacked critical information. Defendants also concealed that they had knowingly submitted (and resubmitted) the application with inadequate supporting data on Defendant Pourhassan's express orders.

87. On July 13, 2020, on this news, the price of the Company's stock dropped by $1.03 per share—nearly 22%—from a close of $4.73 on July 10, 2020 to a close at $3.70 on July 13, 2020.

88. After the July 13, 2020 news was revealed to the market, the Defendants assured investors that the issues the FDA identified with the rejected BLA were not significant.

89. On July 13, 2020, the Company held a Conference Call where Defendant Pourhassan reported: "[t]oday's call is to explain the letter from the FDA requesting information about our BLA filing that has received a Refuse-to-File and did not get the PDUFA date":

> In 2018, CytoDyn announced that the company had hit its primary endpoint in the HIV indication for the MDR population — multi drug-resistant population.
>
> ***
>
> In 2019, CytoDyn met with the FDA on a pre-BLA meeting, and was able to receive a rolling review for its BLA submission. FDA also requested the BLA

> submission should be for a higher dose of 700 milligrams, since the company had shown success with a 700 milligram dose as compared to a 350 milligram dose.
>
> ***
>
> The FDA requested CytoDyn to enroll at least fifty patients and obtain data at 24 weeks with the 700 milligram dose in CD03, which is our monotherapy trial to demonstrate safety of the 700 milligram dose. CytoDyn achieved this in October 2019, and the BLA included information about CD03 trial for the safety portion of the BLA.
>
> ***
>
> ***CytoDyn felt the application was completed for the FDA to provide the PDUFA date***.

90. However, Defendants left out critical information about the data the HIV BLA was missing, attempting to hide the substance of the FDA's RTF Letter from the market. Specifically, during the July 13, 2020 Conference Call noted above, analyst Robert Smith asked: "[i]n the interest of being clear and transparent, why not just share the FDA letter with us, with the shareholders?" Defendant Pourhassan responded: "[L]et me answer the first question. Sharing the FDA letter with the whole public, Now no company that I know give the shareholder the FDA communication to the public."

91. On January 29, 2021, the Company issued a press release, reporting that it had "been working diligently to refile its [BLA] for this HIV combination therapy since receiving a Refusal to File in July 2020 and subsequently meeting with the FDA telephonically to address their written guidance concerning the filing. CytoDyn expects to refile its BLA in the first half of calendar year 2021." The Company expressed the same message through eight subsequent press releases between February and April, 2021.

92. On February 18, 2021, the SEC sent Defendant Mulholland (the CFO of the Company), a letter ("SEC Feb. Letter") regarding the Company's Form 10-K for the Fiscal Year ended May 31, 2020. In the SEC Feb. Letter, the SEC issued targeted inquiries regarding the Company's BLA: (1) the timeline of the Company's communications with the FDA prior to submitting the BLA; (2) how the RTF impacted the Company's timing in respect to efforts to capitalize inventory with respect to leronlimab; (3) the nature of additional information required

by the FDA in order to resubmit the BLA; and (4) "why your projected date for resubmitting the BLA keeps slipping."

93. On March 23, 2021 the Company responded to the SEC Feb. Letter. Then, on April 16, 2021, the SEC issued another letter to Defendant Mulholland ("SEC April Letter"), which claimed that asserted certain responses of the Company failed to sufficiently respond to the SEC's inquiries, including responses "to support management's assertion that prelaunch inventory represented an asset at each date it was capitalized" and questioned the appropriateness of the Company's capitalization conclusions:

> • You assert that your meetings with the FDA addressed safety and efficacy of the drug. However, the FDA's July 2020 Refusal to File letter states that your Biologics License Application omitted information necessary for the FDA to perform a substantive review of the product's safety and effectiveness.
>
> • You indicate that ". . . current scientific work being performed by the Company to complete a successful resubmission of the Company's BLA" is ongoing and that you do not expect to resubmit your BLA until mid- calendar year 2021 or shortly thereafter.
>
> • You assert that you manufactured leronlimab consistent with cGMP standards. However, we note that the FDA's September 20, 2020, response to your list of questions related to the Refusal to File letter continued to reference issues with your clinical and statistical data, device related issues, and chemical manufacturing and control related issues.

94. On May 19, 2021, the SEC sent Defendant Mulholland another letter ("SEC May Letter"). It was in that SEC May Letter that the SEC requested the Company respond to the questions concerning the BLA and also to "[e]nsure you also discuss and update the risks and uncertainties surrounding market acceptance and salability of leronlimab in your future periodic reports."

F. As The HIV BLA Fails, The Company Shifts Its Focus To COVID-19

95. Prior to January 2020, the Company was a small microcap biotech company, trading on the OTC at well under $1.00 per share. For many years, Defendants unsuccessfully sought FDA approval to sell leronlimab to treat HIV patients. However, the Company's HIV BLA had already been delayed months—if not years, due to Defendants' disregard for FDA filing requirements.

96. The COVID-19 pandemic presented Defendants with a perfect opportunity to commit a stock promotion scheme that increased the price of the Company's common shares by 900%, permitting certain defendants to sell tens of millions of Company shares at historically high prices.

1. Defendants' COVID-19 Scheme

97. According to the SEC: "[m]icrocap stocks" like this Company "may be particularly susceptible to stock promotion schemes," including pump-and-dump schemes. "Fraudsters who conduct stock promotions are often . . . company insiders who stand to gain by selling their shares after creating a buying frenzy and pumping up the stock price."

98. Defendants had implemented an infrastructure to create a buying frenzy manufactured by false, misleading, and otherwise unsubstantiated statements and promotional efforts. First, Defendants increased the number of press releases they caused the Company to issue. Historically, the Company issued 30-40 press release in a calendar year. In 2019, the number of press releases the Company issued nearly doubled to 70. In 2020, the number of press releases the Company issued doubled again to 130. The press releases generally contained at least one quote from Defendant Pourhassan, and often quotes from Defendant Kelly. Following these press releases, Defendants held conference calls with investors during which they expanded upon false and misleading statements contained within the press releases.

99. Despite the Company's lack of revenues, Defendants engaged numerous stock promotion websites and services. Defendants paid these stock promotion websites and services to: (a) reissue and amplify the Company's press releases and investor calls; (b) generate friendly interviews of Defendants that resembled materials generated by independent media outlets; (c) host or otherwise moderate calls with investors and the audience of the promotional outlet; (d) issue biased articles and reports reflecting and expanding upon Defendants' false and misleading statements and promotional efforts; and (e) respond to and counteract any negative press about leronlimab.

100. Defendants also issued millions in stock options and warrants to themselves and sold millions of shares on material inside information withheld from the market.

2. Defendants Purport to Explore The Use Of Leronlimab To Treat COVID-19

101. The Company issued the first of more than 150 press releases regarding COVID-19 on January 28, 2020, reporting that the Company was "exploring leronlimab as a potential treatment for [COVID-19] patients." Defendant Pourhassan stated that he "look[ed] forward to advancing discussions with potential partners to study leronlimab as a [COVID-19] treatment option."

102. On February 4, 2020, the SEC's Office of Investor Education and Advocacy issued an Investor Alert entitled *Look Out for Coronavirus-Related Investment Scams*. The SEC had reported that it had "become aware of a number of Internet promotions . . . claiming that the products . . . of publicly-traded companies can prevent, detect, or cure coronavirus, and that the stock of these companies will dramatically increase in value as a result."

103. Ten days after reporting that the Company was "exploring" leronlimab as a potential COVID-19 treatment, Defendants reported on a February 6, 2020 call with the market that they were looking for a partner in China to license leronlimab.

104. On February 12, 2020, the Company issued a press release announcing that it had signed a "nonbinding letter of intent for the joint development and licensing of leronlimab in China with Longen China Group."

105. During a February 24, 2020 interview posted on the Wall Street Reporter website, Defendant Pourhassan confirmed that the "Longen Group" "is working with us right now to get" COVID-19 patients treated with leronlimab. Defendant Pourhassan also stated that the Company was working on another unspecified letter of intent and term sheet and had been "approached . . . by other countries which we will be announcing very soon our agreement with them."

106. On March 5, 2020, a conference call was held by the Company. It was during this call that Defendant Pourhassan reported:

> The next update is in regard to the anticipated timing of potential approval for TFDA Taiwan's FDA of leronlimab for the treatment of cancer[,] HIV[,] and coronavirus[.] [W]e have already signed a letter of intent and NDA . . . with a company which we are not naming at this time in Taiwan. The next update is about doing the same kind of thing in China that we talked about in Taiwan we already have translated all of our documents that we gave to Longen Group and they already indicated that they have submitted it to ask so things and that record have already progress.
>
> ***
>
> The next up update is an overview of doing licensing opportunities. We having licensing opportunities with several countries so in regards to Longen China group, which we announced, we signed a LOI Letter of Intent and NDA. Nine days from today the letter of intent will expire. So they are trying to finish up the final agreement, final term sheet and agreement which we have seen. We are working with them to finish as much as we can, fast as we can. So in regards to the licensing agreement with another company which is a very solid company with financial background located in Taiwan. We will be announcing something shortly with them. We have signed LOI and NDA with them all so now both of these companies are right now talking to us to buy every bit of leronlimab that we have in commercial vials which is 24,000 vials . . . . [N]ow two different entity wants to purchase it and they want to also enter into an agreement to purchase the rest of that. This will come to the point where we will be short of the [vials] especially with coronavirus if we have positive results in the next few weeks hopefully.

107. On this same conference call, Dr. Bruce Patterson ("Dr. Patterson"), a paid Company consultant, reported: "I was in China in January and they were pleased to be able to talk to CytoDyn and no[w] hear about the possibility of bringing leronlimab over to China and now Taiwan . . . first . . . to address the coronavirus situation." Dr. Patterson also stated that "the HIV data and the cancer data" have "[a]ll . . . been submitted to both the CFDA in China and the TFDA in Taiwan as part of an ongoing process to get drug approval over there for coronavirus."

108. However, nothing came to pass concerning the Longen letter of intent or talks with South Korea, China, or Taiwan.

109. As a result, Defendants started to promote their efforts to obtain FDA approval for leronlimab to treat COVID-19. In a March 9, 2020 press release the Company reported that it had filed with the FDA an IND Application to conduct a Phase 2 clinical trial of leronlimab for treatment of COVID-19 in adult patients with mild-to-moderate COVID-19 symptoms ("Phase 2 Trial (CD10)").

110. Following these statements, the Company's promotional machine issued further content regarding the above. For instance, Emerging Growth and Wall Street Reporter republished the March 9, 16, and 23, 2020 press releases on their respective websites. On March 9, 2020, Proactive Investors interviewed Defendant Pourhassan. During the interview, Defendant Pourhassan touted leronlimab as "a solution to coronavirus" and that "[the Company was] are working with other companies right now . . . overseas for this problem."

111. On March 10, 2020, Medical News First ("MN1") posted an article by Pat Monarch entitled *CytoDyn's Vyr[o]logix [leronlimab] to Fight COVID-19 – Hoping to Treat Phase 2 and 3 COVID-19 Patients*. The MN1 article hyped the Company and the use of leronlimab to treat COVID-19.

112. On March 19, 2020, Wall Street Reporter featured Defendant Pourhassan. Defendant Pourhassan made statements about the Company's efforts with respect to COVID-19. On March 23, 2020, an Emerging Growth report expanded upon Defendant Pourhassan's narrative regarding leronlimab's efficacy and safety for COVID-19.

3. As Defendants' COVID-19 Promotional Efforts Continue, Defendants Pourhassan, Mulholland and Kelly Sell $30 Million in Company Common Stock

113. After knowingly filing a materially incomplete HIV BLA on or around April 27, 2020, Defendants doubled-down on their scheme to inflate the price of the Company's common stock by touting leronlimab for COVID-19. Defendants Pourhassan, Mulholland and Kelly sold millions of Company shares for proceeds of more than $30 million beginning April 30, 2020:

Defendant	Date	Number of Shares	Price	Proceeds
Pourhassan	4/30/20	2,219,837	$3.53	$7,838,688.41
	5/1/20	1,399,685	$3.26	$4,569,132
	5/4/20	1,201,652	$2.79	$3,353,089.74
	7/31/20	156,570	$4.97	$778,152.90
	Subtotal			*$16,539,063.05*
Mulholland[3]	12/17/20	32,000	$4.55	$145,673.60
	12/18/20	487,002	$4.95	$2,411,439.10

[3] According to the Form 4 disclosing these transactions, Mulholland's sales were executed pursuant to a Rule 10b5-1 plan entered into on November 12, 2020.

	12/21/20	585,797	$5.58	$3,269,918.85
	12/22/20	245,704	$5.4938	$1,349,848.64
	12/22/20	453,997	$6.6146	$3,003,008.56
	12/22/20	12,100	$7.00	$84,700
	Subtotal			*$10,264,588.75*
Kelly	5/1/20	1,200,000	$3.26	$3,912,480
	Subtotal			*$3,912,480*
	Total			**$30,716,131.80**

114. On April 24, 2020, the Company issued a press release reporting that it would update investors on its HIV BLA and COVID-19 efforts on the next trading day. The price of the Company's stock rose 16%. During an April 27, 2020 conference call, Defendant Pourhassan stated: "[t]o have a solution against COVID-19 is to save humanity from a powerful plague . . . and that brings us to today's most powerful news of CytoDyn's history. In the past, I thought . . . that the BLA filing would be the biggest news of CytoDyn's history. We have news that is by far much larger than the BLA. So allow me to update you on our fight against COVID-19 with leronlimab."

115. Defendant Pourhassan claimed that "[b]lood sample analysis of the first [New York-based COVID-19] patients . . . revealed some exciting news." Defendant Pourhassan reported the results as "impressive" and, later, "remarkable," and stated that "we expect probably several publications surrounding these findings to be out in the next few days and weeks." With respect to the FDA, Defendant Pourhassan also stated: "[w]hen 200 companies run to [the FDA and] say, 'hey, we got the solution to coronavirus! Please say something positive so our stock can go up,'" the FDA "get[s] worried" but "they have given us everything we have asked for."

116. On April 27, 2020, the Company's stock price increased 17%.

117. On April 30, 2020, the Company issued a press release stating "strong results from eIND COVID-19 patients treated with leronlimab." According to the Company: "54 eINDs [have been] approved by [the U.S.] FDA and 49 patients have been treated with leronlimab this far."

118. In this April 30, 2020 press release, the Company also reported "important powerful results from the effect of leronlimab were demonstrated in almost all of these patients,"

and "[t]his data has been submitted to a prestigious journal and ***we expect the publication on Friday, May 1.***" Defendant Pourhassan reported the publication as "our first major paper very close to publication" and hinted at another publication "shortly thereafter."

119. At the same time, Defendants' paid promotional outlets were hard at work. Emerging Growth and Proactive Investors reissued the Company's press releases. On April 30, 2020, Proactive Investor uploaded an interview with Defendant Pourhassan on its website and YouTube. It was during this interview that Defendant Pourhassan promoted the eIND results as "really, really amazing." Defendant Pourhassan further claimed that the Company was "reporting almost 95% or so rate of [eIND] patients being alive and doing better and improved . . . that's a spectacular result[]. And we wanted to make sure everybody knows that." In another May 6, 2020 Proactive Investor interview, Defendant Pourhassan reported that "Dr. Patterson has . . . statistically significant data that means he took the blood of these [eIND] patients and showed why leronlimab work[s]. That should put a lot of doubters' minds at ease that, hey, the mechanism of action is clear."

120. On May 1, 2020, Wall Street Reporter held a "Next Super Stock" livestream where both Defendant Pourhassan and Dr. Patterson participated. When Wall Street Reporter asked Defendant Pourhassan "[w]hy is it so hard for the FDA to realize how many lives can be saved by using leronlimab?" Defendant Pourhassan replied "please don't point fingers at [the] FDA at the time that they're doing a fantastic job separating two hundred companies from the real to fiction. ***Obviously, they believe that we have something here.*** That's why they've been giving us face to face . . . and approval left and right . . . one after another." Further, Dr. Patterson stated "we're looking at the data on how the drug works on COVID and saying, hey, the drug is doing what it's supposed to be doing and that's statistically significant. So we have great, great confidence that because it's been embedded into the trial design that we're going to have a positive outcome."

121. By this point, Defendant Pourhassan had just reaped $7.8 million in insider sales and continued to sell massive amounts of stock shortly thereafter. Indeed, the same day

Defendant Pourhassan was touting leronlimab and its multiple approvals, he dumped almost 1.4 million shares reaping $4.5 million. Defendant Kelly followed suit and dumped 1.2 million shares of Company common stock on May 4, 2020.

4. Defendants Report That The Trial Has Failed To Meet Its Primary Endpoint

122. After falsely promoting the results of the Company's first COVID-19 trial of leronimab, the Phase 2 Trial or CD10, for weeks, Defendant Pourhassan confirmed on July 17, 2020 that the Phase 2 Trial test results were "unblinded now." The next day, July 18, 2020, during an interview that was posted to YouTube, Defendant Pourhassan confirmed that the Phase 2 Trial data was unblinded and "with Amarex" and that he was "hoping to be able to get results on Monday [July 20, 2020] and have a press release on Tuesday [July 21, 2020]." Defendant Pourhassan also speculated: "if we get beautiful results right now, I think the whole world will pay attention."

123. On the trading day after Defendant Pourhassan's above interview on Youtube, the price of the Company's common stock rose 16%.

124. On July 21, 2020, the Company issued a press release reporting "impressive results" from the Company's Phase 2 COVID-19 trial. Proactive Investors reissued this press release on its website. Despite having access to both efficacy and safety data, Defendants chose to tout only the patient safety data, claiming that they still needed to complete "the statistical analyses of all primary and secondary endpoints." According to the July 21, 2020 press release "34% (19 of 56 patients) treated with leronlimab compared to 50% (14 of 28 patients) treated with placebo reported at least one adverse event" and with respect to 19 serious adverse events (SAEs), there were more reported with the placebo (11) than with leronlimab (8), and "[n]one of the SAEs in the leronlimab arm were deemed related to study drug administration by the investigators." In the press release Defendant Kelly emphasized leronlimab's purported safety record, noting that while patients taking leronlimab experienced fewer SAEs than patients taking

the placebo, "[p]rior drugs in clinical trials for the treatment of COVID-19 [i.e., Gilead's remdesivir] have resulted in an increase in SAEs in the drug treated arm versus placebo."

125. That same day, Proactive Investor posted an interview of Defendant Pourhassan on its website and YouTube. During the interview, Defendant Pourhassan reported that "what is missing," e.g., the efficacy data, "is amazing." Defendant Pourhassan further claimed that the Phase 2 Trial (CD10) safety data "itself could be an efficacy for us because . . . that's a fantastic result." Defendant Pourhassan continued "people in the world will now start catching up and we're going to have more data putting out and they're going to realize that we are very serious about getting approval for leronlimab." With respect to the Phase 2 Trial (CD10) efficacy data, Defendant Pourhassan stated that the Company had "something that could shake the world" and that the delay in releasing the efficacy data was due to his "regulatory team and biostatiscian" requesting "time to put this in the right format."

126. During a special meeting of the Company's shareholders on July 22, 2020, Defendant Pourhassan reported "we are very close to be able to submit some solid data [for] our therapy for COVID-19 to the FDA for consideration — for final approval in two separate populations: mild–to-moderate . . . critical and severe." Defendant Pourhassan further stated that "[w]e will stay visible, transparent, and we will report honestly everything that happened in our company as frequently as possible, like usual." Defendant Pourhassan continued "we can't wait to put out the efficacy results"; "we will send to the FDA the whole package [of Phase 2 Trial (CD10) data] and request emergency approval for this indication based on unmet medical need — the nature of this pandemic that we're living right now . . . we might be a few weeks away from potential approval."

127. On July 30, 2020, Defendants held an investor conference call. Regarding the CD10 results, Defendant Pourhassan reported "we do have positive efficacy results. . . . In regards to our primary endpoint, . . . [w]e have seen improvement in day three versus day zero."

128. During the July 30, 2020 call, Defendant Pourhassan also reported that "no one has ever received any positive efficacy results better than placebo in this population in a

randomized double-blinded FDA trials." Defendant Pourhassan also reported "you just heard a fantastic result that nobody has heard, even FDA doesn't have that." Defendant Pourhassan called the results "excellent."

129. That same day, Emerging Growth issued a report entitled *CytoDyn's (CYDY) 100% Above Market Offering Stuns the Street*. Regarding the Phase 2 Trial safety data, the report stated that "[t]he market has really been disconnected from reality with respect to its comprehension of the safety data . . . the safety data from the CD10 trial was jaw dropping . . . leronlimab was about as safe as drinking water." According to Emerging Growth "***[t]he lack of SAE's is an absolute indication of efficacy and likelihood that they met their primary endpoint.*** In ANY randomized double blind placebo controlled study a reduction in SAE's . . . could be a consideration for approval." (Emphasis in original.) The report concluded "[i]nvestors need to wake up and realize that CYDY won the game."

130. On July 31, 2020, Proactive Investors interviewed Defendant Pourhassan, posting the interview on its website and YouTube. During the interview, Defendant Pourhassan stated "[w]e have a product that has shown very strong results. Today we have to all look for positive things that any drug can do and be united. And what we have right now" is "a very positive result" for the National Early Warning Score 2 scale, a secondary endpoint of the Phase 2 Trial, "we think we had a jackpot with that." Pourhassan claimed, "[i]n regards to [the] [P]hase 2 [Trial], this is not a primary endpoint hit or miss phase 3 is where it's do or die."

131. On August 11, 2020, the Company issued a press release, announcing Phase 2 Trial or CD10 "top-line" results, calling them "clinically significant." Proactive Investors reissued this press release on its website. In the press release, the Company reported that leronlimab did not achieve the primary endpoint. Indeed, the Company reported that the primary endpoint of the Phase 2 Trial (CD10) "show[ed] early clinical improvement in symptom score at Day 3 in patients receiving leronlimab" and that "leronlimab also demonstrated statistically significant improvement versus placebo in [a] key secondary efficacy endpoint, National Early Warning Score 2 scale (NEWS2)." The press release quoted Defendant Pourhassan: "Patients

receiving leronlimab showed a statistically significant improvement using NEWS2 clinical parameters. We will make a case for immediate approval of leronlimab for this population of COVID-19 patients, not only in the U.S., but in the U.K. and other countries around the world." The press release also quoted Defendant Kelly stating "The decreased probability in serious adverse events, as well as overall adverse events with leronlimab compared to placebo further supports the use of leronlimab as a treatment option for COVID-19."

132. The fact that the Company had missed the primary endpoint for the Phase 2 Trial was not lost on the market, with the stock price declining throughout the day on August 11, 2020.

133. During the August 12, 2020 investor conference call, Defendant Pourhassan reported that "[a]s of about an hour ago, CytoDyn has requested from the FDA to grant CytoDyn an emergency use authorization for leronlimab based on CD10 data." Defendant Pourhassan further claimed "we are very excited to file for emergency use authorization in many different countries." However, Defendant Pourhassan was forced to admit that the Phase 2 Trial (CD10) had not met its primary endpoint:

> Did we meet our primary endpoint? Meeting your primary endpoint – that means you have a clinically significant value, and if . . . the value is much better in the drug versus placebo, then that becomes statistically significant. If it's not statistically significant, but clinically significant, then your Phase 3 will do the same thing as Phase 2, but with a higher number of patients. So we had that situation. We had the primary endpoint in regards to clinical significance.

134. On August 12, 2020, Proactive Investors posted an interview of Defendant Pourhassan on its website and YouTube. It was in this interview that Defendant Pourhassan reported that the Phase 2 Trial (CD10) "results have been fantastic"; "[t]he problem we have is people don't understand . . . clinical trials, especially laymen, investors. So let me make it very clear. The results were fantastic." Defendant Pourhassan also reported: "[n]ow, the primary endpoint [for CD10] was clinically significant. What does that mean? . . . The difference was 90% versus 70%. If you go to a hospital" and the "rate of getting better" using leronlimab was "90% . . . versus 70% . . . everybody would take that. It's clinically significant." With respect to

potential FDA approval based on CD10, Defendant Pourhassan reported "So let's talk about best case versus worst case. Best case is when [in a] pandemic, mild to moderate is [an] unmet medical need. […] So if the FDA chooses to look at these [CD10] results," and "say, OK," they have clinical significance and "the safety was spectacular. Let's give them emergency approval. That would be fantastic." Pourhassan concluded, "I don't see how anybody in their right mind with one first grade educated person can come over here and say this was bad news about the results."

135. Defendants' false and misleading statements and promotional efforts continued after August 12, 2020. On August 17, 2020, the Company announced that it had submitted the "top-line report" from the Phase 2 Trial to the FDA and "requested emergency use approval" for leronlimab to treat COVID-19 solely on that basis. In an August 19, 2020 press release, Defendants continued to spin the results of the Phase 2 Trial, relying on the fact that it had demonstrated statistical significance in one secondary endpoint to baldly assert that CytoDyn had "statistically significant efficacy findings."

136. Defendants' false and misleading statements and promotional efforts regarding the Phase 2 Trial (CD10) results were repeated by the Company's paid promotional outlets. For example, in an August 17, 2020 Proactive Investors interview, Defendant Pourhassan reported that "there is a lot of negative talk about our company and we are under attack from negative people that are very negative about CytoDyn . . . [our] stock has gone down." Regarding the CD10 trial, Defendant Pourhassan reported "there are two outcomes. Worst case, best case. Best case is the FDA will . . . say . . . [EUA] is granted" and "worst case scenario, we do a Phase 3" trial and "hopefully have approval by the end of the year. I don't know what else we could do to make sure that everybody knows that this is really strong results." Defendant Pourhassan further reported "we . . . look forward to surpris[ing] everybody . . . wh[en] we g[e]t emergency use authorization" in the U.K. or the U.S."

137. Neither the FDA nor the U.K. MHRA granted the Company emergency use authorization of leronlimab for COVID-19. Further, despite informing the market on August 17,

2020 that the Company had formally requested an EUA for leronlimab based solely on the Phase 2 Trial (CD10) results, Defendant Pourhassan changed the narrative again, reporting that the Company had not submitted anything formally to the FDA, but rather had requested its "opinion" about whether an EUA could be granted on the strength of the Phase 2 Trial (CD10) results.

5. As The Phase 2 Trial Missed Its Primary Endpoint, Defendants Switched to Promoting the Company's Phase 3 Trial Results

138. With its Phase 2 Trial (CD10) missing its primary endpoint, Defendants focused their false and misleading statements and promotional efforts to several new areas, including (i) the Company's Phase 2b/3 Trial (CD12); (ii) non U.S. regulatory pathways to approval/authorization; and (iii) a new potential treatment population.

139. On August 4, 2020, the Company announced that it had received a positive Drug Safety Monitoring Committee ("DSMC") recommendation on the CD12 safety data. In an August 17, 2020 press release, Defendant Pourhassan reported to be "in discussions with several regulatory agencies in other countries and hope to obtain emergency approval for its use" and the Company "hope[ed]" that it would "obtain emergency use approval from the MHRA in the U.K., EMA in the European Union, as well as the regulatory authorities in the Philippines." Also, with respect to COVID-19, the Company reported that it had "been approached by several doctors about a clinical study of leronlimab in long-hauler COVID-19 individuals" for which "[t]he Company is preparing a Phase 3 protocol and will file it as soon as possible."

140. On August 19, 2020, the Company reported that it had sent the CD10 "top-line report" to the U.K. MHRA and "requested the regulatory pathway for Fast Track approval noting the efficacy and safety results from the Phase 2 trial." A day later, on August 20, 2020, the Company issued another press release, reporting that the U.K. MHRA had "authorized the Company to enroll for its ongoing" Phase 3 Trial, after "several months of its review of CytoDyn's manufacturing processes and leronlimab's safety profile." Thereafter, the price of the Company's stock increased 25% over two trading days.

141. On August 25, 2020, the Company reported that it had "reached the requisite number of enrolled patients in its Phase 3 [T]rial" such that it could "perform an interim analysis following the 28 day phase of the trial." Defendant Pourhassan stated:

> We are eager to perform an interim analysis of the data and remain optimistic the interim results will be consistent with those experienced by patients who received leronlimab through multiple eINDs (over 60) previously authorized by the FDA. And, in the event we are successful, we are well positioned with our distribution partner to accelerate distribution of leronlimab to patients throughout the U.S.

G. The Truth Begins To Emerge

142. On August 26, 2020, *The Wall Street Journal* reported that CytoDyn was not under consideration for Operation Warp Speed.[4] According to a senior federal official, "CytoDyn had only completed a preliminary qualification for being included in the initiative." Specifically, CytoDyn had submitted information through CoronaWatch, a program run by the Biomedical Advanced Research and Development Authority to assess the viability of drugs and therapeutics that might be effective against COVID-19. Technical experts had reviewed the submission and opted not to proceed further at this time, the official confirmed. Moreover, the official noted that the team reviewing the submissions had made clear to companies that the submissions are for informational purposes only and do not by themselves lead to funding; companies must apply to specific grant programs to receive funding, which CytoDyn had not done.

143. On this news, the Company's share price fell $0.66, or 17%, over two consecutive trading sessions to close at $3.15 per share.

144. With the walls closing in, Defendants attempted to keep the stock price artificially inflated. On September 2, 2020, the Company reported that the U.K. MHRA granted it a meeting to discuss its request for Fast Track approval of leronlimab to treat COVID-19. Defendants also held a conference call on that day with investors to discuss its COVID-19 efforts. The

[4] https://www.wsj.com/articles/small-biotech-stock-cytodyn-soars-on-warp-speed-comment-11598456736

Company's stock price increased 38% over four consecutive trading days (September 2-4 and 8, 2020).

145. On September 3, 2020, the SEC filed suit against Illiad, Iliad's principal John Fife ("Fife"), and certain Fife-related entities (Chicago Venture Partners L.P., St. George Investments LLC, Tonaquint, Inc., and Typenex Co-Investment, LLC). Specifically, the SEC alleged that Iliad and its related entities operated as unregistered securities dealers in violation of the federal securities laws by buying convertible promissory notes, converting the notes into newly issued shares of stock, then rapidly selling those shares into the public at a profit. Calling Fife a "recidivist violator of the federal securities laws," the SEC alleged that these entities violated the mandatory dealer registration requirements of the federal securities laws. *See Securities and Exchange Commission v. John M. Fife, et al.*, Case No. 1:20-cv-05227, Complaint (N.D. Ill. Sept. 3, 2020). Iliad had operated as an unregistered securities dealer and generated substantial profits by, among other things, entering into the convertible promissory note with CytoDyn, converting the note into newly issued shares, and selling them into the market at a profit.

146. On September 16, 2020, defendant Pourhassan admitted that no formal EUA request had been made to the FDA. Instead, CytoDyn had only asked for the FDA's opinion, with defendant Pourhassan stating "we did not submit a formal letter to FDA saying we want to get Emergency Use Authorization. We asked them for their opinion and they were not positive about it. Their reasoning made a lot of sense to us." *See* Moon Kil Woong, *CytoDyn's Update Provides A Clear Path Towards Approval With Up-Listing Potential Still In The Cards*, TALKMARKETS (Sept. 18, 2020).

147. On September 17, 2020, CytoDyn was sued by a stock promoter called Shift Media Lab for the failure to pay for its stock promotion services. In its complaint filed in the 11th Judicial Circuit for the Miami-Dade County, Florida, Shift Media Lab alleged that it had provided "services" to CytoDyn for three months at $25,000 per month. According to CytoDyn's disclosure statement to the OTCQB Venture Market, Shift Media Lab provided "Brand Awareness" for CytoDyn.

148. On November 10, 2020, CytoDyn entered into an amended $28.5 million Secured Convertible Promissory Note with Fife's company, Streeterville Capital LLC, a related entity that was not specifically named in the SEC action against Iliad and Fife.

149. On this news, the Company's stock price closed at $2.02, representing an 80% decline from its highs during the wrongdoing.

150. On March 5, 2021, after the market closed, CytoDyn began issuing press releases that described the results of Phase IIb/III testing data for Leronlimab for the treatment of COVID-19. Masked by positive titles, these releases disclosed that the primary endpoint for the study (lowering all-cause mortality at Day 28) was not statistically significant. For example, in a press release entitled "CytoDyn to File Accelerated Rolling Review with MHRA and Interim Order (IO) with Health Canada for COVID-19," the Company stated:

> ***Amongst all patients in mITT, the primary endpoint (all-cause mortality at Day 28) was not statistically significant.*** When age adjustment was conducted, the primary endpoint was much closer to statistically significant value. Of note, the reduction of mortality in this population of 65 years and younger leronlimab arm had more than 30% less mortality than placebo and 9% less mortality in participants over 65.

151. With the age adjustment analysis in all other major secondary endpoints, there was consistent numerical superiority over the placebo group, with some secondary endpoints approaching statistical significance.

152. On this news, the Company's share price fell $1.14, or 28%, to close at $2.91 per share on March 8, 2021. On March 9, 2021, CytoDyn shares dropped an additional 19% to close at $2.35 per share.

153. On May 17, 2021, the FDA took the nearly unprecedented step of issuing a public statement on an unapproved drug:

> FDA recognizes the substantial public interest in medicines that are being studied for the prevention or treatment of COVID-19, especially those medicines that may provide a benefit to patients with the most severe forms of disease that can result in respiratory failure and death. Leronlimab, a monoclonal antibody investigational drug under development by CytoDyn, Inc. (CytoDyn), is one of the potential medicines that has been studied to determine whether it is safe and effective in treating patients with COVID-19, including those with severe outcomes from COVID-19.

* * *

> With the conclusion of both the CD10 and CD12 clinical trials, ***it has become clear that the data currently available do not support the clinical benefit of leronlimab for the treatment of COVID-19.*** In the smaller study that CytoDyn conducted in patients with mild-to-moderate COVID-19 disease (CD10), there was no observed effect of the drug on the study's primary endpoint or on any of the secondary endpoints…. Additionally, none of the secondary endpoints were met in this study, including mortality, time to symptom resolution, and time to return to normal activity. Taken together, the CD10 results indicate that most study participants experienced resolution in COVID-19 symptoms regardless of whether they received leronlimab or placebo

* * *

> ***CytoDyn has publicly communicated differences in small subgroups from the CD12 trial (e.g., a sub-group analysis of 62 of the 394 patients studied) suggesting that the data demonstrated a mortality benefit in certain patients who had received leronlimab. Subgroup analyses have well-established limitations, especially in the context of a clinical trial that has failed to show a benefit in the overall study population…. None of these analyses met statistical significance when using established and reliable analytical methods that correct for multiple comparisons.*** However, as noted above, such analyses may inform the design of future clinical trials investigating leronlimab for the treatment of COVID-19

154. On July 30, 2021, the Company disclosed the investigations by the SEC and U.S. Department of Justice. The Company has received "subpoenas from the SEC requesting documents and information concerning, among other matters, leronlimab, the Company's public statements regarding the use of leronlimab as a potential treatment for COVID-19 and related communications with the FDA, investors, and others, and trading in the securities of CytoDyn." In addition, the Company and certain of Defendants received subpoenas in connection with an investigation being conducted by the United States Department of Justice. The "subpoenas seek testimony and/or records concerning, among other matters, leronlimab, the Company's public statements regarding the use of leronlimab as a potential treatment for COVID-19 and related communications with the FDA, investors, and others, and trading in the securities of CytoDyn."

V. THE COMPANY'S CORPORATE GOVERNANCE

155. As members of the Company's Board, the law holds the Director Defendants to the highest standards of honesty and integrity and charges them with overseeing the Company's

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business practices and policies and assuring the integrity of the Company's financial and business records.

156. The conduct of the Director Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of the Company, the absence of good faith on their part, and a reckless disregard for their duties to the Company and its investors that the Director Defendants were aware posed a risk of serious injury to the Company.

A. The Audit Committee Charter

157. According to the Company's 2019 proxy statement filed August 21, 2019, "[t]he primary role of the Audit Committee is to oversee the financial reporting and disclosure process."

158. The Company maintains an Audit Committee Charter. The Audit Committee Charter states in relevant part:

> To review with management and the Company's independent auditors the adequacy and effectiveness of the Company's financial reporting processes, internal control over financial reporting and disclosure controls and procedures, including any significant deficiencies or material weaknesses in the design or operation of, and any material changes in, the Company's processes, controls and procedures and any special audit steps adopted in light of any material control deficiencies, and any fraud involving management or other employees with a significant role in such processes, controls and procedures, and review and discuss with management and the Company's independent auditors disclosure relating to the Company's financial reporting processes, internal control over financial reporting and disclosure controls and procedures, the independent auditors' report on the effectiveness of the Company's internal control over financial reporting, where applicable, and the required management certifications to be included in or attached as exhibits to the Company's annual report on Form 10-K or quarterly report on Form 10-Q, as applicable.

159. The purpose of the Audit Committee is to assist the Company's Board in its oversight of accounting, financial reporting and disclosure processes and adequacy of systems of disclosure and internal controls. The wrongful conduct of the Director Defendants complained of herein violates the Charter of the Audit Committee.

B. Duties Of The Director Defendants

160. By reason of their positions as officers and/or directors of the Company, and because of their ability to control the business and corporate affairs of the Company, the Director

Defendants owed the Company and its investors the fiduciary obligations of trust, loyalty, and good faith. The obligations required the Director Defendants to use their utmost abilities to control and manage the Company in an honest and lawful manner. The Director Defendants were and are required to act in furtherance of the best interests of the Company and its investors.

161. Each director of the Company owes to the Company and its investors the fiduciary duty to exercise loyalty, good faith, and diligence in the administration of the affairs of the Company and in the use and preservation of its property and assets. In addition, as officers and/or directors of a publicly held company, the Director Defendants had a duty to promptly disseminate accurate and truthful information regarding the Company's operations, finances, and financial condition, as well as present and future business prospects, so that the market price of the Company's stock would be based on truthful and accurate information.

162. To discharge their duties, the officers and directors of the Company were required to exercise reasonable and prudent supervision over the management, policies, practices, and controls of the affairs of the Company. By virtue of such duties, the officers and directors of the Company were required to, among other things:

(a) ensure that the Company complied with its legal obligations and requirements, including acting only within the scope of its legal authority and disseminating truthful and accurate statements to the SEC and the investing public;

(b) conduct the affairs of the Company in an efficient, businesslike manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock;

(c) properly and accurately guide investors and analysts as to the true financial condition of the Company at any given time, including making accurate statements about the Company's business prospects, and ensuring that the Company maintained an adequate system of financial controls

such that the Company's financial reporting would be true and accurate at all times;

(d) remain informed as to how the Company conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, make reasonable inquiries in connection therewith, take steps to correct such conditions or practices, and make such disclosures as necessary to comply with federal and state securities laws;

(e) ensure that the Company was operated in a diligent, honest, and prudent manner in compliance with all applicable federal, state and local laws, and rules and regulations; and

(f) ensure that all decisions were the product of independent business judgment and not the result of outside influences or entrenchment motives.

163. Each Director Defendant, by virtue of his or her position as a director and/or officer, owed to the Company and to its shareholders the fiduciary duties of loyalty, good faith, and the exercise of due care and diligence in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets. The conduct of the Director Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of the Company, the absence of good faith on their part, and a reckless disregard for their duties to the Company and its shareholders that the Director Defendants were aware, or should have been aware, posed a risk of serious injury to the Company.

164. The Director Defendants breached their duties of loyalty and good faith by causing the Company to issue false and misleading statements concerning the business opportunities, results, and prospects of the Company. As a result, the Company has expended, and will continue to expend, significant sums of money related to investigations and lawsuits.

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VI. ADDITIONAL FALSE STATEMENTS

165. During 2020 and into 2021, even after the truth had begun to emerge, Defendants caused the Company to make a series of materially false and misleading statements regarding: (a) the HIV BLA; (b) the efficacy and safety of leronlimab for COVID-19; and (c) the results of the Phase 2 Trial (CD10) and Phase 2b/3 Trial (CD12).

A. The HIV BLA

166. On April 9, 2020, the Company filed a Form 10-Q for the fiscal quarter ended February 29, 2020. In the Form 10-Q, the Company stated:

> The Company's inventory as of February 29, 2020 and May 31, 2019 was $15,895,589 and $0, respectively. Inventory as of February 29, 2020 consisted solely of specialized raw material purchased for use in the commercial manufacturing of pre-launch inventories of Vyrologix to support the Company's expected approval of the product as a combination therapy for HIV patients in the United States. The Company believes that all material uncertainties related to the ultimate regulatory approval of Vyrologix for commercial sale have been significantly reduced based on positive data from Phase III clinical trial results, information gathered from pre-filing meetings with the Food and Drug Administration for the Biologics License Application ("BLA"), and the Company's anticipated filing of the BLA with the FDA targeted for the end of April 2020.

167. On April 27, 2020, the Company released a press release entitled, *CytoDyn Submits Completed Biologics License Application (BLA) to the FDA for Leronlimab as a Combination Therapy for Highly Treatment Experience HIV Patients*. In that press release, the Company stated that "CytoDyn completed the filing of its BLA in April 2020 to seek FDA approval for leronlimab as a combination therapy for highly treatment experienced HIV patients."

168. In that same press release, Defendant Pourhassan stated that "[w]ith the BLA filing for a combination therapy now complete, we are continuing our efforts on commercialization-readiness, as well as advancing leronlimab in the other important therapeutic areas of COVID-19, cancer and immunology. The BLA filing is a monumental achievement for our Company."

169. On April 27, 2020, the Company issued another press release entitled, *CytoDyn Announces Vyrologix as Proprietary Name for Leronlimab as a Combination Therapy for Highly Treatment Experienced HIV Patients in the United States*. The press release stated: "CytoDyn completed the filing of its BLA in April 2020 to seek FDA approval for leronlimab as a combination therapy for highly treatment experience HIV patients."

170. On that same day, during a Company Investor Community Call, Defendant Pourhassan reported that: (a) "The first update is the BLA submission, which is a historical achievement for CytoDyn . . ."; (b) "The good news is, CytoDyn just filed the full BLA last night"; (c) "So in short, ladies and gentlemen, the BLA is submitted"; and (d) "The BLA got filed."

171. A few days later, on April 29, 2020, the Company issued a press release entitled *CytoDyn's Drs. Pourhassan and Patterson to Present Live at Wall Street Reporter's Event to Discuss Paper Recently Submitted for Publication and Positive Results of eIND COVID-19 Patients*. The press release stated that the Company had "completed the filing of its BLA in April 2020 to seek FDA approval for leronlimab as a combination therapy for highly treatment experienced HIV patients."

172. The next day, on April 30, 2020, the Company issued a press release entitled *CytoDyn Reports Strong Results from eIND COVID-19 Patients Treated with Leronlimab; Majority of Patients Have Demonstrated Remarkable Recoveries* in which the same language was implemented.

173. On May 4, 2020, the Company issued a press release entitled *FDA Approves Emergency INDs for Leronlimab Treatment of Coronavirus CytoDyn Requests Compassionate Use from FDA for COVID-19 Patients Not Eligible for Participation in Two Ongoing Clinical Trials in U.S. – CytoDyn Targets Enrollment Completion for its 75 Patient, Phase 2 Trial by End of May*. The press release stated that "[the BLA] will be considered completed after the clinical datasets are submitted on May 11, 2020."

174. On May 6, 2020, the Company issued a press release entitled *Manuscript Describes How CytoDyn's Leronlimab Disrupts CCL5/RANTES-CCR5 Pathway, Thereby Restoring Immune Homeostasis, Reducing Plasma Viral Load, Reversing Hyper Immune Activation and Inflammation in Critical COVID-19 Patients*. The press release stated that "[w]e would like to provide an update that the Biologics License Application (BLA) for Leronlimab as a Combination Therapy for Highly Treatment Experienced HIV Patients will be considered completed after the clinical datasets are submitted on May 11, 2020. The clinical datasets are updated to address FDA comments for mock datasets from March 12 and March 20, 2020."

175. On May 8, 2020, the Company issued a press release entitled "*CytoDyn Clarifies Status of Biologics License Application* in which it stated: (a) "The BLA will not be considered completed until the Company submits to the FDA clinical datasets required to address FDA comments it received in March 2020, as described in the Company's press releases on May 4 and May 6, 2020. CytoDyn expects to submit these clinical datasets on May 11, 2020"; (b) "The Company filed its BLA for Leronlimab as a Combination Therapy for Highly Treatment Experienced HIV Patients to the FDA on April 27, 2020"; and (c) "CytoDyn filed its BLA in April 2020 to seek FDA approval for leronlimab as a combination therapy for highly treatment experienced HIV patients, and plans to submit additional datasets needed to complete the BLA on May 11, 2020."

176. On May 13, 2020, the Company issued a press release entitled *CytoDyn Completed Submission of All Remaining Parts of Biologics License Application ("BLA")* on May 11, 2020. The press release stated that the Company "confirmed" that "on May 11, 2020, it submitted all remaining parts of the Company's Biologics License Application ('BLA') for leronlimab as a combination therapy with HAART for highly treatment experienced HIV patients to the [FDA]. Pursuant to FDA guidelines, CytoDyn informed the FDA it had submitted a complete BLA for rolling review."

177. The Company further stated in the May 13, 2020 press release that "[t]he Company filed its BLA for Leronlimab as a Combination Therapy for Highly Treatment

Experienced HIV Patients to the FDA on April 27, 2020 and submitted the additional FDA requested clinical datasets on May 11, 2020."

178. And, the Company further stated in the May 13, 2020 press release that "CytoDyn filed its BLA in April 2020 to seek FDA approval for leronlimab as a combination therapy for highly treatment experienced HIV patients, and submitted additional FDA requested clinical datasets on May 11, 2020."

179. On May 15, 2020, the Company issued a press release entitled, *CytoDyn to Offer No-Cost Exploratory Laboratory Testing for Childhood Inflammatory Disease Associated with COVID-19*. The press release stated that "[t]he Company filed its BLA for Leronlimab as a Combination Therapy for Highly Treatment Experienced HIV Patients with the FDA on April 27, 2020, and submitted additional FDA requested clinical datasets on May 11, 2020" and "CytoDyn filed its BLA in April 2020 to seek FDA approval for leronlimab as a combination therapy for highly treatment experienced HIV patients, and submitted additional FDA requested clinical datasets on May 11, 2020."

180. The Company made identical statements to the market in press releases issued on (and titled): (i) May 18, 2020 (*CytoDyn to Prepare a Phase 3 Protocol to Submit to the FDA for a Three-Arm Comparative and Combination Trial of Leronlimab and Remdesivir*); (ii) May 19, 2020 (*CytoDyn and the Mexican National Institutes of Health Participate in a Collaborative Study of Leronlimab for the Treatment of Severe/Critical COVID-19 Population*); (iii) June 1, 2020 (*CytoDyn Files Request With FDA for Priority Review of BLA for First Approval*); (iv) June 8, 2020 (*CytoDyn Receives BLA Acknowledgment Letter From the FDA*); (v) June 11, 2020 (*CytoDyn Reached Its Enrollment Target for Phase 2 COVID-19 Trial for Mild to Moderate Indication – Primary End Point Announcement Is Next*); (vi) June 11, 2020 (*CytoDyn Initiates Phase 2 Clinical Trial with Leronlimab for Treatment of Nash*); (vii) June 29, 2020 (*CytoDyn and NIH of Mexico Complete Memorandum of Understanding to Conduct Small Covid-19 Phase 3 Trial for Severe and Critically Ill Patients*); (viii) July 2, 2020 (*CytoDyn Releases Mechanism of Action Animation for Leronlimab in Immuno-Oncology*); (ix) July 3, 2020 (*CytoDyn*

Announces Execution of Exclusive Agreement with American Regent for Distribution and Supply of Leronlimab for Treatment of COVID-19 in United States); (x) July 6, 2020 (*CytoDyn Announces Execution of Exclusive Agreement with American Regent for Distribution and Supply of Leronlimab for Treatment of COVID-19 in United States*); and (xi) July 7, 2020 (*CytoDyn's Leronlimab Prevents Transmission of SHIV in Macaque Study*).

181. On May 15, 2020, during an interview, Defendant Pourhassan stated that the "BLA [was] already submitted."

182. On May 20, 2020, during an interview, Defendant Pourhassan stated that he believed the HIV BLA was a "complete package."

183. On May 26, 2020, during an interview, Defendant Pourhassan stated that the HIV BLA was "submitted with rolling review."

184. On July 4, 2020, in statements made during an interview entitled, Leronlimab Discussion with Dr. Been, Defendant Pourhassan reported:

> We said in, I believe April 27th, that we submitted the full BLA. FDA immediately said 'no, we don't agree'. And we immediately set [sic] to the public that it is not completed. It's going to be completed in a few more days, and it was.

185. On July 8, 2020, the Company issued two press releases. In those press releases the Company reported:

> "CytoDyn filed its BLA in April 2020 to seek FDA approval for leronlimab as a combination therapy for highly treatment experienced HIV patients, and submitted additional FDA requested clinical datasets on May 11, 2020."

186. The statements set forth in ¶¶166-185 were false and misleading when made because Defendants knew or were reckless in not knowing that the Company lacked various types of data that were critical to the HIV BLA and was not capable of submitting a complete HIV BLA in the time frame specified. For instance, the Company did not possess data, information, or analyses the FDA had expressly stated were required to be submitted in the HIV BLA, including: (a) complete bioanalytical reports; (b) full validation data for all PPQ lots analyzed; (c) complete CCR5 receptor occupancy data for 350 mg, 525 mg, and 700 mg doses;

(d) analyses of Anti-Drug Antibodies (ADA) or any assessment of association between ADA and virlogic failure; and (e) multiple reports needed for the FDA to permit a substantive review. Thus, the statements about the anticipated submission date of the HIV BLA in April 2020 and reporting that the Company did not have evidence that the HIV BLA would be denied, and the Company's counting of its leronlimab supplies as an inventory asset, lacked a reasonable basis in fact.

187. Moreover, the statements set forth above in ¶¶166-185 reporting that the BLA was; e.g., "complete" and/or "completed," "filed," and/or "submitted" were false and misleading. Specifically, at the time these statements were issue, the Company misrepresented, concealed, and/or failed to disclose that:

(a) The CEO of Amarex, the Company's CRO that was performing the overall development of the HIV BLA, including managing multiple data analyses and essential projects, specifically warned Defendant Pourhassan prior to April 14, 2020 that the HIV BLA was incomplete;

(b) On April 14, 2020, Defendant Pourhassan ordered that the HIV BLA be submitted in April 2020 regardless of known shortcomings. In an April 14, 2020 e-mail, Pourhassan directed the BLA be filed in April 2020 "no matter what portion of whatever it is that we are short." As Amarex's CEO has stated in a sworn declaration: "Pourhassan directed Amarex to file the BLA prematurely, knowing it was incomplete, lacking in appropriate content and not ready for submission";

(c) The Company (and HIV BLA) lacked data that the FDA had expressly told the Company in the June 2018 Pre-BLA Meeting must be included in a complete application "at the time of the BLA submission," including "complete bioanalytical reports" and "full validation data from all PPQ lots";

(d) The Company (and HIV BLA) lacked data that the FDA had expressly told the Company in the December 14, 2018 teleconference must be included in a complete

application, including "data from studies conducted with the drug in the device," and "information on the manufacturer of the syringe and needles";

(e) The Company (and HIV BLA) lacked data that the FDA had expressly told the Company in the January 2019 MPPRC Meeting and in its December 16, 2019 correspondence to the Company must be included in a complete application, including "CCR5 receptor occupancy data" for three separate doses sizes. The Company had only representative data for two sizes;

(f) The Company (and HIV BLA) lacked data that the FDA had expressly told the Company must be included in a complete application, including "a Pop PK analysis to support the selection of a higher dose [700 mg, based on the dose-finding study in the monotherapy study (CD03)] than the dose evalutated in the pivotal trial (CD02)";

(g) The Company (and HIV BLA) lacked data that the FDA had expressly told the Company in its January 22, 2019 correspondence must be included in a complete application, including "analyses of Anti-Drug Antibodies (ADA) or any assessment of any association between ADA and virologic failure";

(h) The Company (and HIV BLA) lacked data that the FDA had expressly told the Company in its November 11, 2019 correspondence must be included in a complete application, including "an integrated assessment of efficacy," and adequate efficacy comparisons as between the dose group and randomized arms of the study; and

(i) The Company (and HIV BLA) lacked data that the FDA had expressly told the Company in its December 16, 2019 correspondence must be included in a complete application, including: (i) "the information and analyses needed to permit FDA reviewers (clinical, statistical, clinical virology and clinical pharmacology) to perform a substantive review of the proposed dose"; (ii) "an integrated assessment that incorporates detailed summaries reflecting data from the participants randomized to receive 350 mg, 525mg, and 700mg in CD03 and for the 350 mg dose evaluated in HTE MDR patients in CD02"; and (iii) "multiple reports that are needed to permit a substantive review."

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188. By speaking publicly about the Company's purported complete HIV BLA submission and datasets and/or information that the FDA requested, Defendants had a duty to fully, completely, and truthfully disclose all material facts regarding the HIV BLA submission and there was no reasonable basis to misrepresent that the HIV BLA submission was properly filed or that the Company submitted the datasets and/or information that the FDA actually requested.

B. COVID-19

1. Statements Regarding Efficacy and Safety of Leronlimab

189. On May 1, 2020, Defendant Pourhassan and Dr. Patterson participated in Wall Street Reporter's Next Super Stock livestream. It was during that May 1, 2020 livestream, Dr. Patterson reported:

> And then to be able to publish with statistical significance the findings encoded that underlie why Leronlimab will work before the statistical significance comes from the trials is -- is a source of great excitement because there's two levels of clinical significance. Obviously, we have to let the FDA do their thing. We are absolutely on board with that and doing it the right way with the FDA. But at the end of the day, we—we're looking at the data on how the drug works on COVID and saying, hey, the drug is doing what it's supposed to be doing and that's statistically significant. So we--we have great, great confidence that because it's been embedded into the trial design that we're going to have a positive outcome, at least in my opinion.

190. On June 2, 2020, Defendant Pourhassan and Dr. Lalezari participated in Wall Street Reporter's Next Super Stock livestream. It was during this June 2, 2020 livestream that Defendant Pourhassan reported: "[a]s we said, you know, the unblinding we will have for CD10, very much likely on June 15th, and of the June, the primary endpoint will be read out to the world, and we hope to shock the world with the very beautiful results."

191. During that same livestream on June 2, 2020, in response to a question from an audience member about where leronlimab would rank "in comparison to all time successful drugs[,]" Dr. Lalezari reported:

> "I'm not sure I want to speculate too much on the future, but I -- I will say that if we look at the rest of the COVID-19 landscape, there's no other drug that is showing this kind of antiviral effect. […] So, yes, it is utterly amazing how well and that effect is being seen in 100 percent of patients. So, you know, I don't—I'm wary of the future […] As I said, there's no precedent for this, that a new

> drug—you would know a drug would work from emergency IND data before you even understood how it was working or even before you had randomized clinical studies. So I think Nader is doing a great job to try and match reality with leronlimab, with what is happening. But the—certainly the potential is that this is ground breaking and the world has never seen anything like it, and in my heart of hearts, I think this drug's a home run. And in my heart of hearts, I wish we'd had it approved six weeks ago and maybe could have saved the first hundred thousand lives, but yes, this story is going to have a huge impact. And my biggest concern would be making sure there's enough drugs to treat everybody in the world who's going to need it. That's at the end of the day. That's going to be the biggest challenge."

192. On the June 2, 2020 livestream, responding to a question as to what data existed to show that "patients improved as a result of leronlimab and not just a spontaneous resolution of the virus[,]" Dr. Lalezari commented: "[t]he results are even more astonishing because as a group, these patients were so ill and so terminal. But it doesn't seem to me to be a huge stretch to take the data in patients who are terminal and then see in the [e]IND results evidence of the same clinical benefit."

193. The statements above in ¶¶189-192 were false and misleading, omitted material facts because Defendants knew or were deliberately reckless in not knowing that the FDA had not determined that leronlimab was safe or efficacious in any indication, including HIV, cancer, and COVID-19 and that, per the FDA, "the data currently available do not support the clinical benefit of leronlimab for the treatment of COVID-19."

2. Statements Regarding The Phase 2 Trial (CD10) Results

194. On August 12, 2020, the Company held a conference call. It was during this call that Defendant Pourhassan reported:

> In regards to our study, many questions have come. Did we meet our primary endpoint? Meeting your primary endpoint — that means you have to have a clinically significant value, and if it's the value is much better in the drug versus placebo, then that becomes a statistically significant. If it's not statistically significant, but clinically significant, then your Phase 3 will do the same thing as Phase 2, but with a higher number of patients.
>
> So, we had that situation. We had the primary endpoint in regards to clinical significance.
>
> ***
>
> But, something happened to these trials. Something fantastic we have discovered. We discovered that there is a secondary endpoint that we believe is even more

> important than our primary endpoint, and we have achieved a statistically significant value for that, which is the so-called NEWS2. NEWS2, which is the updated version of NEWS. N-E-W-S, which is National Early Warning Score. NEWS2 assess the degree of illness that points out to any need for critical care intervention. This means we lowered this risk of having this combination of seven parameters that constitute the NEWS score, and we have done it by [1]50% better than placebo.
>
> ***
>
> And these seven parameters are very important parameters. Just look at them. Their respiratory rate, oxygen saturation, supplemental oxygen, temperature, systolic blood pressure, heart rate, and level of consciousness. So, these are very important parameters that are used to give you a score. Our score was 50% in leronlimab versus 20% in placebo. That was statistically significant. That means the risk of critical-care intervention due to use of leronlimab was reduced by two-and-half times. And our safety has been very amazing.

195. During the same conference call, Defendant Kelly reported: "We just showed statistical significance in a randomized, double-blinded, placebo-controlled study from a tool that helps identify which patients will deteriorate and require prompt critical care intervention [NEWS2]. I think that's remarkable."

196. In addition, in response to the following question, Defendant Kelly stated: "I . . . read the statistical significance on Day 3, in terms of the clinical response. But at Day 10 and 14, there was no difference between the drug and placebo, or there was a difference, but it did not reach statistical significance?"

197. Defendant Pourhassan also stated: "So day seven and fourteen for symptom score in the pre-protocol, it was not significant. So we didn't even talk about it. We only talk about the one that had clinical significance – three days, which we thought it was the most important part."

198. On August 17, 2020, the Company issued a press release entitled *CytoDyn Submits its Top-Line Report from its Phase 2 COVID-19 Trial to the U.S. FDA and Requests Emergency Use Approval*. It was in that press release that Defendant Pourhassan stated:

> We believe the statistically significant data of NEWS2 findings, along with impressive safety results (less SAEs or AEs with leronlimab vs. placebo), from our Phase 2 trial set forth in the Top-line Report provides compelling data in support of leronlimab's use to fight COVID-19. We are in discussions with several regulatory agencies in other countries and hope to obtain emergency approval for its use.

199. On August 19, 2020, the Company issued a press release entitled *CytoDyn Requests 'Fast Track Approval' for COVID-19 Patients from U.K.'s Regulatory Agency MHRA based on its Top-line Report Showing Statistically Significant Endpoint, NEWS2 (p <0.023) and Notably Safety Results*. It was in that press release that Defendant Pourhassan again touted the Phase 2 Trial (CD10) "statistically significant efficacy findings."

200. On August 20, 2020, the Company issued a press release entitled *After Several Months of Providing Requested Information About Manufacturing and Safety of Leronlimab, U.K.'s MHRA Accepts CytoDyn's Request to Enroll in its Current Phase 3 Trial for COVID-19 Patients with Severe-to-Critical Symptoms*. It was in that press release that Defendant Pourhassan likewise touted the Phase 2 Trial (CD10) as having "strong efficacy and safety data."

201. The statements in ¶¶194-200 were materially false and misleading because Defendants knew or were deliberately reckless in not knowing that the FDA had not determined that leronlimab was safe or efficacious in any indication, including HIV, cancer, and COVID-19. The statements asserting that the Phase 2 Trial (CD10) had showed "clinical significance" with respect to its primary endpoint and "statistically significant" with respect to the NEWS2 secondary endpoint and otherwise provided "compelling data" for leronlimab's use to treat COVID-19 were false and misleading because Defendants knew or were deliberately reckless in not knowing that, per the FDA: (a) "the data currently available," including Phase 2 Trial (CD10), "do not support the clinical benefit of leronlimab for the treatment of COVID-19"; (b) "there was no observed effect of the drug on the study's primary endpoint or on any of the secondary endpoints"; (c) "[t]he [Phase 2] CD10 trial results showed no clinically meaningful differences in average change in 'total clinical symptom score' from baseline to Day 14 between study arms"; (d) "none of the secondary endpoints were met in this study, including mortality, time to symptom resolution, and time to return to normal activity"; and (e) "the [Phase 2] CD10 results indicate that most study participants experienced resolution in COVID-19 symptoms regardless of whether they received leronlimab or placebo."

202. On March 5, 2021, the Company issued a press release entitled, *CytoDyn's Phase 3 Trial Demonstrates Safety, a 24% Reduction in Mortality and Faster Hospital Discharge for Mechanically Ventilated Critically Ill COVID-19 Patients Treated with Leronlimab* ("March 5, 2021 Press Release"). In the March 5, 2021 Press Release, the Company disclosed that the Phase 2b/3 Trial (CD12) "demonstrated continued safety, substantial improvement in the survival rate, and faster hospital discharge in critically ill COVID-19 patients."

203. The March 5, 2021 Press Release also stated that: (a) "[t]here was a 24% reduction in all-cause mortality (primary endpoint of the study) in the leronlimab versus placebo"; (b) "[t]he average length of hospital stay was reduced by 6 days for patients who received leronlimab with 'commonly used COVID-19 treatments,' also referred to as 'Standard of Care' or 'SoC,' compared to placebo patients who received SoC only, with a statistically significant p-value of 0.005"; and (c) "patients who received leronlimab demonstrated an improved probability of 'discharged alive' at Day 28 (28% versus 11%), a 166% better rate than the placebo group."

204. Defendant Pourhassan stated in the March 5, 2021 Press Release:

> Our [Phase 2b/3] CD12 study demonstrates leronlimab is particularly effective in treating [critically ill COVID-19 patients]. We believe these results are the best results ever achieved for this population in a Phase 3 clinical trial [. . .] leronlimab demonstrated a reduction of 24% in mortality compared to the SoC treated group, which is 12 times better in reducing all-cause mortality for critically ill COVID-19 patients. The Company is very excited about these results and is concurrently working with regulators here and abroad to expedite leronlimab's approval to treat COVID-19.

205. On March 6, 2021, the Company issued a press release entitled, *CytoDyn to File Accelerated Rolling Review with MHRA and Interim Order (IO) with Health Canada for COVID-19*" ("March 6, 2021 Press Release") "announc[ing] . . . multiple regulatory pathways for approval of leronlimab as a treatment for critical COVID-19 patients in the U.S. It was in this March 6, 2021 Press Release that the Company stated that it was "pleased to show strong data for critically ill COVID-19 patients."

206. The March 6, 2021 Press Release also reported:

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> [A]n "age adjustment" analysis was performed and consequently, the updated results from the primary endpoint analysis are as follows:
>
> 1) Statistically significant results (p-value = 0.0319) reported for the primary endpoint (all-cause mortality at Day 28) in participants receiving leronlimab + "commonly used COVID-19 treatments" compared to participants who received "commonly used COVID-19 treatments" alone in the placebo group in the overall modified intent-to-treat ("mITT") population.
>
> 2) Statistically significant results (p-value = 0.0552) reported for the primary endpoint (all-cause mortality at Day 28) among participants who received dexamethasone as the prior or concomitant standard of care treatment ("SoC") for COVID-19, compared to patients who received dexamethasone (without leronlimab) as SoC therapy in the overall mITT population.
>
> 3) Amongst all patients in mITT, the primary endpoint (all-cause mortality at Day 28) was not statistically significant. When age adjustment was conducted, the primary endpoint was much closer to statistically significant value. Of note, the reduction of mortality in this population of 65 years and younger leronlimab arm had more than 30% less mortality than placebo and 9% less mortality in participants over 65.
>
> With the age adjustment analysis in all other major secondary endpoints, there was consistent numerical superiority over the placebo group, with some secondary endpoints approaching statistical significance.

207. The Company reissued the March 5, 2021 Press Release and the March 6, 2021 Press Release on March 8, 2021.

208. Further, on March 8, 2021, the Company issued a press release entitled, *CytoDyn to Release CD12 Trial Detailed Results via Form 8-K After Investment Community Webcast, Monday, March 8* ("March 8, 2021 Press Release"). The March 8, 2021 Press Release included the statements set forth above.

209. The statements in ¶¶202-208 were false and misleading because Defendants knew or were deliberately reckless in not knowing that the FDA had not determined that leronlimab was safe or efficacious in any indication, including HIV, cancer, and COVID-19.

210. Defendants' statements asserting the Phase 2b/3 Trial (CD12) "show[s] strong data" and "demonstrates" that leronlimab is "particularly effective in treating critically-ill" COVID-19 patients, and that Defendants had "multiple regulatory pathways for approval of leronlimab as a treatment for critical COVID-19 patients in the U.S." and were using the Phase 2b/3 Trial (CD12) to "expedite leronlimab approval" were false and misleading because

Defendants knew or were deliberately reckless in not knowing that per the FDA: (a) the Phase 2b/3 Trial (CD12) "failed to find any effect of the drug on the primary study endpoint, with no difference seen in mortality (20.5% in the leronlimab treatment group and 21.6% in the placebo treatment group); or on any of the secondary endpoints, for example, with no difference on the average length of hospitalization (21.4 days in both the leronlimab and the placebo treatment groups)"; (b) the Phase 2b/3 Trial (CD12) subgroup analyses "do not support reliable conclusions about the medicine's benefit" where, as here, "the analyses of the primary and secondary endpoints do not support conclusions of the medicine's benefit"; (c) "[s]ubgroup analyses have well-established limitations, especially in the context of a clinical trial [such as this one] that has failed to show a benefit in the overall study population"; (d) "[f]ocusing on only the most favorable of many subgroup analyses, even if the sub-groups are pre-specified, can lead to overestimating the evidence of benefit, because regardless of a drug's true efficacy, some analyses are likely to appear favorable by chance when a large number of analyses are conducted"; and (e) "[n]one of th[e subgroup] analyses" for Phase 2b/3 Trial (CD12) "met statistical significance when using established and reliable analytical methods that correct for multiple comparisons."

211. In addition, Defendants' statements that Phase 2b/3 Trial (CD12) "demonstrated . . . substantial improvement in the survival rate" of critically ill patients and a "24% reduction in all-cause mortality rate (the primary endpoint of the study)" in critically ill patients, and the "age adjusted analysis" and "updated results from the primary endpoint analysis" for three different subgroups were materially false and misleading, omitted material facts, and lacked a reasonable basis when made because Defendants knew but did not disclose that the Phase 2b/3Trial (CD12) "failed to find any effect of the drug on the primary study endpoint," and also per the FDA: (a) the analysis of "subgroup[s]"—here, critically-ill patients, patients taking leronlimab + standard of care, all mITT9 patients, and mITT patients taking leronlimab + dexamethasone—"do not support reliable conclusions about the medicine's benefit" where, as here, "the analys[i]s of the primary . . . endpoint[] do[es] not support

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conclusions of the medicine's benefit"; and (b) "[n]one of th[e subgroup] analyses" for Phase 2b/3 Trial (CD12) "met statistical significance when using established and reliable analytical methods that correct for multiple comparisons."

212. Moreover, the statements that the Phase 2b/3 Trial "demonstrated an improved probability of 'discharged alive' at Day 28" and a "statistically significant" reduction in the "average length of hospital stay . . . by 6 days" in the subgroup of patients that took leronlimab + the standard of care were false and misleading because Defendants knew but did not disclose that the Phase 2b/3 Trial (CD12) "failed to find any effect of the drug . . . on any of the secondary "mITT" refers Modified Intention-to-Treat. The "Intention-to-Treat" principle requires that all participants in a randomized study be included in the final analysis and analyzed according to their assigned treatment group regardless of what happened during the patient's participation in the study. There is no clear definition of "mITT" as it can vary from trial to trial, but effectively, mITT indicates that some participants were excluded when the results were unblinded endpoints," and per the FDA: (a) the Phase 2b/3 Trial (CD12) subgroup analyses "do not support reliable conclusions about the medicine's benefit" where, as here, "the analys[i]s of the . . . secondary endpoints do not support conclusions of the medicine's benefit"; (b) "[s]ubgroup analyses have well-established limitations, especially in the context of a clinical trial [such as this one] that has failed to show a benefit in the overall study population"; and (iii) "[n]one of th[e subgroup] analyses" for Phase 2b/3 Trial (CD12) "met statistical significance when using established and reliable analytical methods that correct for multiple comparisons."

213. In addition, on March 8, 2021, a conference call was held. During the call, Defendant Pourhassan stated that CD12 "showed [a] statistically significant secondary endpoint."

214. Moreover, at this conference call, Chief Scientific Officer Mahboob Rahman ("Rahman") stated: "if you look at the data . . . even in the overall population, you will see consistently in essentially all different endpoints, you see a benefit, maybe numerical, but you see a benefit consistently." Rahman also stated:

> we . . . prespecified the critically ill patients as one of the subpopulations that we will test our primary and secondary endpoint. And if you look at those prespecified analysis, you will see that this – the mortality was reduced by 24% in this critically ill patient population, which was defined as ordinal scale 2, which means intubated – either just intubated or on ECMO. These patients, 24% mortality was reduced.
>
> Then if you look at the time to recovery or discharge from hospitals, our hospital stay in this patient population, you actually see a statistically significant difference, 6 days less in this patient population. And another secondary endpoint, which is called discharge alive through day 28, and in here, we see a pretty wide difference between the patient who received leronlimab, 28%, versus patients who only received standard of care, 11%, a 166% better rate than placebo.
>
> So with these results in this critically ill patient population, we think that regulatory authorities will take a very close look and see if there is a potential for saving lives under the conditions that we are in right now, with essentially no medication having an impact in the mortality and benefit in the critically ill population.

215. Also, during this conference call, Defendant Pourhassan reported:

> Critically ill population, we've shown relative reduction in mortality of 24%. In regard to the whole population, we talk about 309 patients severe and critical. What happened when they took were commonly used drugs and leronlimab versus placebo, and we talk about 233 patients that took dexamethasone with leronlimab versus dexamethasone and placebo.

216. Defendant Pourhassan and Rahman had the following response to questions posed by Arian Colachis ("Colachis"), the Company's Vice President ("VP"), General Counsel and Secretary:

> COLACHIS: . . . ClinicalTrials.gov named all-cause mortality as the primary endpoint. Why report the 24% reduction in all-cause mortality without a p-value?
>
> POURHASSAN: We discussed that. We put the p-value for primary endpoint. Critical yield was another primary endpoint.
>
> COLACHIS: The press release does not support a p-value for shortened time to recovery but nowhere is shortened time to recovery listed as an endpoint at ClinicalTrials.gov. Do you want a future trial protocol to include this as an endpoint?
>
> ***
>
> RAHMAN: Maybe in the ClinicalTrials.gov, it is listed as hospital stay – length of hospital stay, which is the same as essentially shortened time to recovery. We just made it more understandable in terms of lingo but it's the same. And that is one of the secondary endpoint, and that is the one that was statistically significant in the critically ill population.

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217. In response to the following question posed by Colachis: "What is the difference between overall mortality and probability of being discharged alive?", Defendant Pourhassan and Rahman stated:

> POURHASSAN: So discharged alive was ordinal scale of 2. Everybody was scored between 1 to 7, 1 being dead to being on invasive mechanical ventilator, intubated in ICU. And 7 was released from hospital with no problem. 6 was released from hospital with some minor problems. So those patients who walk out with OS 2 and they received a score of 6 to 7, and that's what we evaluated at the time of discharge because 6 and 7 means discharged.
>
> ***
>
> RAHMAN: So to explain it simply, overall mortality is patients who died. And discharged alive not only takes into account whether you're alive but also takes into account that you are well enough to leave the hospital. So it's a combination of being alive and well enough to leave the hospital. So you may be alive, but you're not in a condition to leave the hospital by day 28 because that's also a benefit. And as I said before, in this endpoint, you see that the patients who received leronlimab, 28% of them were able to leave the hospital by day 28, whereas only 11% of the standard of care. So--so yes, so it takes into account death as well as how well you are feeling if you're alive.

218. On March 8, 2021, the Company filed with the SEC a Form 8-K (the "EXECUTIVE SUMMARY CD12_COVID-19 STUDY 04-MAR-2021") ("March 8, 2021 Form 8-K").

219. With respect to the Phase 2b/3 Trial (CD12) results, the March 8, 2021 Form 8-K stated:

> Survival benefit: A favorable, statistically significant results (p value 0.0319) reported for the primary endpoint (all-cause mortality at Day 28) in participants receiving leronlimab + "commonly used COVID-19 treatments" compared to participants who received "commonly used COVID-19 treatments" alone in the placebo group in the overall mITT population.
>
> Similar statistically significant results (p value 0.0552) reported for the primary endpoint (all-cause mortality at Day 28) among participants who received dexamethasone as the prior or concomitant standard of care treatment for COVID-19, compared to patients who received dexamethasone (without leronlimab) as standard of care therapy in the overall mITT population.
>
> ***
>
> Shortened time to recovery: The average length of hospital stay was lower in leronlimab group compared to placebo/SoC group in the critically ill population with a statistically significant p value of 0.0050 using the Rank-ANCOVA model.
>
> ***

> Leronlimab improved the probability of "discharged alive" at Day 28 in the overall mITT population as well as in the critically ill population with the results trending towards statistical significance.

220. The March 8, 2021 Form 8-K also reported: "The safety analysis of leronlimab in COVID-19 patients was found consistent with the established extensive safety profile with over 1000 patients treated across other multiple studies and indications."

221. The March 8, 2021 Form 8-K also reported: "The potential benefit of adding leronlimab to SoC was consistently seen in the critically ill patient population by virtue of numerically better results for all pre specified evaluated clinical endpoints."

222. The statements in ¶¶213-221 were false and misleading because Defendants knew or were deliberately reckless in not knowing that the FDA had not determined that leronlimab was safe or efficacious in any indication, including HIV, cancer, and COVID-19. Defendants' statements that leronlimab's "safety profile" was "established," the Phase 2b/3 Trial (CD12) "consistently" showed "a benefit" "in essentially all endpoints" "even in the overall population" as well as in "critically ill patient[s]" taking leronlimab with "SoC" "for all pre-specified evaluated clinical endpoints" were false and misleading because Defendants knew or were deliberately reckless in not knowing that per the FDA: (a) the Phase 2b/3 Trial (CD12) "failed to find any effect of the drug on the primary study endpoint, with no difference seen in mortality (20.5% in the leronlimab treatment group and 21.6% in the placebo treatment group); or on any of the secondary endpoints, for example, with no difference on the average length of hospitalization (21.4 days in both the leronlimab and the placebo treatment groups)"; (b) the Phase 2b/3 Trial (CD12) subgroup analyses "do not support reliable conclusions about the medicine's benefit" where, as here, "the analyses of the primary and second endpoints do not support conclusions of the medicine's benefit"; (c) "[s]ubgroup analyses have well-established limitations, especially in the context of a clinical trial [such as this one] that has failed to show a benefit in the overall study population"; (d) "[f]ocusing on only the most favorable of many subgroup analyses, even if the sub-groups are pre-specified, can lead to overestimating the evidence of benefit, because regardless of a drug's true efficacy, some analyses are likely to

appear favorable by chance when a large number of analyses are conducted"; and (e) "[n]one of th[e subgroup] analyses" for Phase 2b/3 Trial (CD12) "met statistical significance when using established and reliable analytical methods that correct for multiple comparisons."

223. Defendants' statements that Phase 2b/3 Trial (CD12) also demonstrated a "[s]urvival benefit" including "favorable, statistically significant results . . . reported for the primary endpoint" in two subgroups (leronlimab + SoC and leronlimab + dexamethasone) and a "relative reduction in mortality of 24%" in a "pre-specified" critically ill patient subgroup were false and misleading because Defendants knew or were deliberately reckless in not knowing that also per the FDA: (a) the Phase 2b/3Trial (CD12) "failed to find any effect of the drug on the primary study endpoint," and, per the FDA; (b) the analysis of "subgroup[s]"—here, critically-ill patients, patients taking leronlimab + SoC, all mITT patients, and mITT patients taking leronlimab + dexamethasone—"do not support reliable conclusions about the medicine's benefit" where, as here, "the analys[i]s of the primary . . . endpoint[] do[es] not support conclusions of the medicine's benefit"; and (c) "[n]one of th[e subgroup] analyses" for Phase 2b/3 Trial (CD12) "met statistical significance when using established and reliable analytical methods that correct for multiple comparisons."

224. Defendants' statements that the Phase 2b/3 Trial also demonstrated "shortened time" for recovery, including a "statistically significant" reduction in "average length of hospital stay" in critically ill patient subgroup, "[l]eronlimab improved the probability of 'discharged alive'" in two subgroups (overall mITT population and critically ill patients), and CD12 "showed a statistically significant endpoint" were false and misleading because Defendants knew or were deliberately reckless in not knowing that per the FDA: (a) the Phase 2b/3 Trial (CD12) "failed to find any effect of the drug . . . on any of the secondary endpoints"; (b) the Phase 2b/3 Trial (CD12) subgroup analyses "do not support reliable conclusions about the medicine's benefit" where, as here, "the analys[i]s of the . . . secondary endpoints do not support conclusions of the medicine's benefit"; (c) "[s]ubgroup analyses have well-established limitations, especially in the context of a clinical trial [such as this one] that has failed to show a benefit in the overall study

population"; and (d) "[n]one of th[e subgroup] analyses" for Phase 2b/3 Trial (CD12) "met statistical significance when using established and reliable analytical methods that correct for multiple comparisons."

225. On March 30, 2021, the Company issued a press release entitled *CytoDyn's Leronlimab Decreased Mortality at 14 Days by 82% With Statistically Significant P-Value of 0.0233 Amongst Critically Ill COVID-19 Patients*. The press release reported:

> Upon further statistical analysis of the critically ill population (hospitalized patients receiving invasive mechanical ventilation (IMV) or ECMO), it was revealed that when leronlimab was added to standard of care ("SoC"), leronlimab decreased mortality at 14 days by 82% (p=.0233, N=62). Patients who received leronlimab were over five times more likely to be alive at day 14 than those who received SoC only.
>
> Furthermore, leronlimab administration was associated with a 400% improvement in the ranking on the 7-point ordinal scale at 14 days when given in conjunction with SoC (p=.021, N=62) in the critically ill population, which provides direct evidence of tangible patient improvement.

226. The March 30, 2021 press release also provided:

> This analysis builds upon the previously released information from the Company's mITT analysis of CD12 showing:
>
> • A clear benefit when leronlimab was used in addition to "commonly used COVID-19 treatments," in the primary endpoint of all-cause mortality at day 28 with an absolute risk reduction of death of 6.5% and a relative risk reduction of death of 28.1% (N=309, p=.0319).
>
> • A clear benefit when leronlimab was used in combination with dexamethasone, in the primary endpoint of all-cause mortality at day 28 with an absolute risk reduction of death of 5.7% and a relative risk reduction of 26.0% (N=233, p=.0552).
>
> • Length in hospital stay decreased by 5.5 days in the critically ill population (N=62, p=.005).
>
> • A clear trend toward mortality benefit at day 28 with an absolute risk reduction of death of 20.9% and a relative risk reduction of death of 73% when leronlimab was used in addition to "commonly used COVID-19 treatments" in the critically ill population with an age ≤ 65 years old.
>
> • A clear trend toward mortality benefit at day 28 with an absolute risk reduction of death of 16.3% and a relative risk reduction of death of 73.5% when leronlimab was used in addition to dexamethasone in the critically ill population ≤ 65 years old.

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227. The March 30, 2021 press release also quoted Defendant Pourhassan: "The Company believes this new information bolsters the case for immediate use of leronlimab for critically ill patients. Furthermore, we believe these results suggest that to see maximum effect of leronlimab at day 28, we must use three to four doses of leronlimab and not just two doses, as was the case with CD12 (day zero and day 7 only)."

228. The statements set forth above in ¶¶225-227 were false and misleading because Defendants knew or were deliberately reckless in not knowing that the FDA had not determined that leronlimab was safe or efficacious in any indication, including HIV, cancer, and COVID-19. The statements that (a) "further statistical analysis" of the critically ill subgroup demonstrated a statistically significant reduction of mortality at 14 days and "direct evidence of tangible patient improvement" on the ordinal scale, (b) the new "analysis" showed a "clear" mortality "benefit" or a "clear trend toward [a] mortality benefit" in various subgroups, and (c) the purportedly "new information" in the March 30, 2021 Press Release "bolster[ed] the case for immediate use of leronlimab for critically ill patients" were false and misleading because Defendants knew or were deliberately reckless in not knowing that per the FDA: (i) the Phase 2b/3 Trial (CD12) "failed to find any effect of the drug on the primary study endpoint, with no difference seen in mortality (20.5% in the leronlimab treatment group and 21.6% in the placebo treatment group); or on any of the secondary endpoints, for example, with no difference on the average length of hospitalization (21.4 days in both the leronlimab and the placebo treatment groups)"; (ii) the Phase 2b/3 Trial (CD12) subgroup analyses "do not support reliable conclusions about the medicine's benefit" where, as here, "the analyses of the primary and secondary endpoints do not support conclusions of the medicine's benefit"; (iii) "[s]ubgroup analyses have well- established limitations, especially in the context of a clinical trial [such as this one] that has failed to show a benefit in the overall study population"; (iv) "[f]ocusing on only the most favorable of many subgroup analyses, even if the sub-groups are pre-specified, can lead to overestimating the evidence of benefit, because regardless of a drug's true efficacy, some analyses are likely to appear favorable by chance when a large number of analyses are conducted"; and (v) "[n]one of

th[e subgroup] analyses" for Phase 2b/3 Trial (CD12) "met statistical significance when using established and reliable analytical methods that correct for multiple comparisons."

VII. DAMAGES TO THE COMPANY

229. As a direct and proximate result of the Individual Defendants' conduct, CytoDyn has been seriously harmed and will continue to be. Such harm includes, but is not limited to:

(a) Any funds paid to settle the Securities Class Action;

(b) Costs, including expenses, professional fees, and penalties, incurred in connection with the SEC and DOJ investigations;

(c) Ill-gotten gains from Defendants' insider stock sales; and

(d) Costs incurred from compensation and benefits paid to the defendants who have breached their duties to CytoDyn.

230. In addition, CytoDyn's business, goodwill, and reputation with its business partners, regulators, and shareholders have been gravely impaired. The Company still has not fully admitted the nature of its false statements and the true condition of its business. The credibility and motives of management are now in serious doubt.

231. The actions complained of herein have irreparably damaged CytoDyn's corporate image and goodwill. For at least the foreseeable future, CytoDyn will suffer from what is known as the "liar's discount," a term applied to the stocks of companies who have been implicated in illegal behavior and have misled the investing public, such that CytoDyn's ability to raise equity capital or debt on favorable terms in the future is now impaired.

VIII. DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS

232. Plaintiffs bring this action derivatively in the right and for the benefit of CytoDyn to redress injuries suffered, and to be suffered, by CytoDyn as a direct result of breaches of fiduciary duty by the Individual Defendants and contribution for violations of Section 10(b) of the Exchange Act. CytoDyn is named as a nominal defendant solely in a derivative capacity. This is not a collusive action to confer jurisdiction on this Court that it would not otherwise have.

233. Plaintiffs will adequately and fairly represent the interests of CytoDyn in enforcing and prosecuting its rights.

234. Plaintiffs have continuously been shareholders of CytoDyn at times relevant to the wrongdoing complained of and are current CytoDyn shareholders.

235. When this action was filed,[5] CytoDyn's Board of Directors consisted of defendants Kelly, Pourhassan, Naydenov, Timmins, and Patel. Plaintiffs did not make any demand on the Board to institute this action because such a demand would be a futile, wasteful, and useless act, as set forth below.

The Entire Board Faces A Substantial Likelihood Of Liability

236. At all relevant times, CytoDyn has had one product candidate. Leronlimab is the Company's core business, indeed, the Company's only business. Each of Kelly, Pourhassan, Naydenov, Timmins, and Patel had a fiduciary obligation to be informed of material developments regarding leronlimab. In the event that Kelly, Pourhassan, Naydenov, Timmins, and Patel discharged that obligation and were informed, they knew that the Company was pervasively issuing false statements regarding its core business. In the alternative, if Kelly, Pourhassan, Naydenov, Timmins, and Patel were so woefully uninformed regarding the Company's core business as to be unaware that the public disclosures were pervasively false and misleading, they face a substantial likelihood of liability for failing to act in good faith and inform themselves regarding the wrongdoing at the Company. Due to the foregoing, and the allegations herein, demand is excused as to each of Kelly, Pourhassan, Naydenov, Timmins, and Patel.

Pourhassan, Kelly, And Naydenov Face A Substantial Likelihood Of Liability Due To Misleading Statements Issued Regarding the HIV BLA

237. Leronlimab was the Company's sole drug candidate, so the HIV BLA presented the first opportunity for CytoDyn to commercialize leronlimab and generate revenue. Thus, Pourhassan and Kelly (as executive officers) and Naydenov (as a member of the Audit

[5] The lead case in this consolidated action was filed on June 4, 2021.

Committee) knew or were reckless in not knowing that the HIV BLA was deficient when it was filed.

238. Specifically, they knew or were reckless in not knowing that the FDA had identified certain data that was required to be included in CytoDyn's HIV BLA based on the following:

(a) In a June 2018 pre-BLA meeting, the FDA "requested" that CytoDyn "submit complete bioanalytical reports (reports which describe analysis of concentrations of leronlimab in blood samples collected in the clinical trials)."

(b) During a December 14, 2018 teleconference, the FDA "reiterated" that the failure to submit the following information would be considered grounds for a "Refusal to File:" "CMC [Chemistry Manufacturing Controls] information, an agreed upon iPSP and final results from a Human Factors study."

(c) Following a January 2019 MPPRC meeting, the Division of Antivirals related that it had "asked about the CCR5 receptor occupancy data for the 350 mg, 525 mg and 700 mg doses."

(d) Correspondence prior to January 16, 2019 in which the FDA "requested a Pop PK analysis to support the selection of a higher dose [700 mg, based on the dose-finding study in the monotherapy study (CD03)] than the dose evaluated in the pivotal trial (CD02)." (Alteration in original.).

(e) Correspondence dated January 22, 2019 identifying that "a detailed narrative to explain whether or not [Anti-Drug Antibodies ("ADA")] is associated with virologic failure" to allay the agency's concerns that ADA "may impact leronlimab effectiveness."

(f) Correspondence dated November 11, 2019 "that explain[ed] the importance of displaying CD03 data by randomization group; and

(g) December 16, 2019 correspondence stating that CytoDyn "should submit an integrated assessment and detailed summary that supports [its] selected dose [700 mg]," which

> incorporates virologic outcomes, safety data (including laboratory abnormalities), exposure related data (including population pharmacokinetics and exposure-response relationship analyses), receptor occupancy data (including both method validation report and bioanalytical report of clinical samples), and anti-idiotypic data (including both method validation report and bioanalytical report of clinical samples).

239. The assessment "should reflect data from the 3 doses evaluated in CD03 and for the 350 mg dose evaluated in HTE MDR patients in CD02."

240. Pourhassan specifically knew that the HIV BLA was incomplete when it was submitted on or about April 27, 2020. On April 14, 2020, Pourhassan emailed Dhody, Kazempour, and Nitya Ray (CytoDyn's Chief Technology Officer) directing them to "file the BLA no later than next week Wednesday, ***even if we are short in no matter what portion of whatever it is that we are short.***" His email makes clear that he was motivated to do so because CytoDyn's stock price continued to decline following repeated delays in the submission, which deteriorated the value of his holdings and the potential value of the options that would only vest when CytoDyn submitted the HIV BLA (*see* ¶253, *infra*):

> Dear Nitya and Kush:
>
> Today we have so far in 1 hour almost 20% drop in our stock price. Yesterday we had drop also after putting out great results about COVID-19 patients we are seeing these type[s] of decline.
>
> This drop will be much deeper if we don't file our BLA as the message board is now getting bombarded by investors who are very frustrated with me and CytoDyn.
>
> Please file the BLA no later than next week Wednesday, ***even if we are short in no matter what portion of whatever it is that we are short.***

241. Despite knowing that the HIV BLA suffered fatal deficiencies when submitted on April 27, 2020, Pourhassan, Kelly, and Naydenov issued or caused CytoDyn to issue misleading statements touting the "complete" submission as a "monumental achievement." Although the Company walked back some of these statements over the next few days, the HIV BLA was still incomplete after CytoDyn submitted certain clinical datasets on May 11, 2020. As alleged herein, the FDA's RTF Letter issued on July 8, 2020 identified the deficiencies in the

Company's BLA submission, all of which Pourhassan knew CytoDyn was required to submit. Specifically, the RTF letter confirmed that the HIV BLA did not include:

(a) bioanalytical reports describing analysis of concentrations of leronlimab in blood samples;

(b) "data from studies conducted with the drug in the device" and information "on the manufacturer of the syringe and needles";

(c) required receptor occupancy data, instead including "only representative data from 525 mg and 700 mg in the receptor occupancy report, which itself "does not adequately address numerous methodologic[al] concerns";

(d) Pop PK analysis consistent with the FDA's guidance;

(e) "analyses of [ADA] or any assessment of any association between ADA and virologic failure";

(f) "an integrated assessment of efficacy" because, among other things, "the comparisons of effectiveness by dose . . . were conducted by dose group instead of between the randomized arms"; and

(g) "an integrated assessment that incorporates detailed summaries reflecting data from the participants randomized to receive 350 mg, 525 mg, and 700 mg in CD03 and for the 350 mg dose evaluated in HTE MDR patients in CDO2" and other information to enable the FDA "to perform a substantive review of the proposed dose."

242. The substance of the RTF Letter was not public until October 26, 2021, when it was filed in litigation between Amarex and CytoDyn. Pourhassan, while in possession of the RTF Letter, downplayed the deficiencies and misleadingly claimed that he "felt the application was completed for the FDA to provide the PDUFA date." These statements are wholly implausible, given the significant deficiencies noted in the RTF Letter and the fact that CytoDyn has yet to obtain the additional clinical data and refile the HIV BLA.[6]

[6] After repeated delays, CytoDyn now claims it expects to resubmit the clinical section of the BLA by the end of the first calendar quarter of 2022.

243. For the foregoing reasons, Pourhassan, Kelly, and Naydenov face a substantial likelihood of liability for breach of fiduciary duty, thus they could not disinterestedly consider a demand and demand is futile as to them.

Pourhassan, Kelly, And Naydenov Face A Substantial Likelihood Of Liability In Connection With Misleading Statements Issued RegardingLeronlimab As A Potential Treatment For COVID-19

244. On May 17, 2021, the FDA issued a statement on leronlimab recognizing, in relevant part, that "[w]ith the conclusion of both the CD10 and CD12 clinical trials, it has become clear that the data currently available do not support the clinical benefit of leronlimab for the treatment of COVID-19." The FDA's comments plainly contradict the statements that Pourhassan, Kelly, and Naydenov caused CytoDyn to issue touting the purported "statistically significant" results from the CD10 and CD12 trials, as alleged herein. When pressed whether the FDA was merely targeting the Company for "moving outside the U.S. to conduct its trial" by issuing a statement rebuking the Company's claims, Pourhassan conceded "the FDA has not done anything wrong. We did something wrong."

Pourhassan, Together With Kelly And Naydenov, Wields Significant Influence Over The Board

245. Pourhassan, together with Kelly and Naydenov, wields significant influence over the Board such that the remaining directors could not independently consider a demand. By late 2019, many of CytoDyn's directors and officers had been ousted due to their disagreements with Pourhassan, especially related to his executive compensation, and replaced by Pourhassan's loyalists.

Pourhassan Forces Out Those Who Fail to Acquiesce to His Desires and Actions

246. At the start of CytoDyn's fiscal 2019 year on June 1, 2018, the Board was comprised of Pourhassan, Kelly, Naydenov, Carl Dockery ("Dockery"), Gregory A. Gould ("Gould"), Denis R. Burger ("Burger"), A. Bruce Montgomery ("Montgomery"), and Anthony Caracciolo ("Caracciolo"). By September 2019, the Board was significantly restructured: Burger,

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Caracciolo, Montgomery, Dockery, and Gould resigned or were removed, and Michael A. Klump ("Klump") and David F. Welch ("Welch") were installed.

247. Burger, Caraccoilo, and Montgomery resigned by the end of 2018 after pushing back on Pourhassan's demands for increased compensation. During his first five years as CEO from 2013 to 2018, Pourhassan received total annual compensation of $447,552 (of which $72,659 was stock option awards), $615,406 ($96,406 in stock option awards), $1,323,824 ($696,335), $1,143,298 ($456,660), $966,561 ($293,201), respectively, which far exceeded the CEO compensation of similarly situated peer companies like Xenetic Biosciences, Inc. ($318,333 in 2018) and AmpliPhi Biosciences Corporation ($618,000 in 2018). Nevertheless, "[a]t almost every Board meeting, Pourhassan would begin with a presentation about all the things he was doing for the Company and the financial sacrifices he had purportedly made . . . to complain that he was underpaid and entitled to additional (but undeserved) compensation." Dockery, Gould, and Caracciolo contend that "Pourhassan made no secret of the fact that he placed his own financial interests above protecting the Company's work and future."

248. In July 2019, Pourhassan ousted CytoDyn's then-Chief Medical Officer, Richard Pestell, after Dr. Pestell "raised concerns regarding certain actions taken by the CEO, including but not limited to actions in connection with public representations" and "regulatory submissions." According to Dr. Pestell's later lawsuit, his relationship with Pourhassan "rapidly deteriorated following Dr. Pestell's objections in late June 2019" to an Investigational New Drug Application protocol that CytoDyn planned to submit to the FDA "despite the fact that Dr. Pestell . . . determined that the protocol . . . was not safe for the study subjects." On July 1, 2019, Pourhassan emailed the Board seeking permission to terminate Dr. Pestell for cause and appoint Kelly as CMO. When this did not come to fruition, Pourhassan proposed (and the Board approved) appointing Kelly as Chief Science Officer and giving him many of Dr. Pestell's CMO responsibilities. The Company's proxy statements identify that Kelly is "a practicing physician and writer" with directorships at various medical associations, but he is not qualified by training or experience in biotech companies to warrant the management position. When Dr. Pestell sent a

letter from his counsel regarding the foregoing, Pourhassan engineered a Board meeting at which Dr. Pestell was terminated for cause.[7]

249. Dr. Pestell's exit in turn sparked the removal of Gould and Dockery from CytoDyn's Board. Gould had objected to the proposed termination of Dr. Pestell, so "Kelly intentionally put the matter to a Board vote when he knew Gould would be on an airplane and unavailable . . . after expressly telling Gould that he [Kelly] would not put Pestell's termination to a vote while Gould was not available." Dockery had alerted CytoDyn's auditor and the rest of the Board to Pourhassan's conduct, especially false and misleading statements to investors in December 2018 that CytoDyn would submit the HIV BLA by "the first quarter of 2019" when Pourhassan and others "were informed that Q1 2019 was not a realistic timeframe."8 On July 30, 2019, the Board voted to remove Dockery and Gould from the slate of directors that would stand for reelection. *See Alpha Venture Capital Partners LP et al. v. Pourhassan et al.*, Case No. 2020-0307 (Del. Ch.), ("*Alpha Venture* Complaint"), at ¶ 81. Gould then resigned in August 2019 and Dockery served on the Board until September 12, 2019, the date of the 2019 Annual Meeting.

250. Klump resigned from the Board on January 15, 2020 amid a dispute to award 11.65 million stock options to insiders, including Pourhassan, who had already received more than 9 million options in excess of their annual award. *Alpha Venture* Complaint, at ¶¶ 119-120.

Pourhassan, Kelly, and Naydenov Are Forced to Forfeit Substantial Stock Awards

251. Thus, by September 2019, the Board was comprised of Pourhassan, Kelly, Naydenov, Klump, and Welch. The Compensation Committee consisted of Naydenov and

[7] The litigation regarding Dr. Pestell's termination is ongoing. *See Pestell v. CytoDyn Inc. et al.*, Case No. 19-cv-1563-RTD (D. Del.).

[8] Dockery also noted that the Board had discussed with Pourhassan that public statements "needed to involve the Board and go through a more rigorous process to ensure their accuracy and tone," at which point Pourhassan "attempted to fire the attorney at Lowenstein Sandler LLP [CytoDyn's outside corporate counsel] that had been attempting to help him with press releases and public statements" but "Pestell and [Dockery] prevented that from happening." After Dr. Pestell and Dockery were forced out of the Company, Lowenstein Sandler LLP, was either terminated or resigned by January 2020.

Welch, but CytoDyn had already identified that Welch was not independent due to his consulting arrangement as "Strategic Advisor" for the Company. His service on the committee violated the Compensation Committee charter, which requires that its members be independent directors.

252. On December 19, 2019, Pourhassan, Kelly, Klump, Naydenov, and Welch awarded themselves and four other insiders 9.3 million stock options and warrants. This award was unrelated to the usual course of business because directors had already been awarded their annual grant – non-employee directors received 100,000 stock options in June 2019 with an exercise price of $0.52 per share, the closing price of the Company's stock on the date of the grant; Pourhassan received 375,000 stock options under the Incentive Plan in October 2019; and Kelly and Welch each received 187,500 stock options in October 2019. Moreover, the December 2019 Awards were the "result of a hastily called night-time meeting Pourhassan initiated and which resulted in the immediate granting of an out-of-schedule award." *Alpha Venture* Complaint, ¶ 117.

253. Pourhassan was the beneficiary of a substantial part of the December 2019 award. He received 4 million stock options/warrants; Kelly received 1.25 million; Klump, Naydenov, and Welch each received 750,000; and Mulholland received 700,000. Approximately half of the awards to Pourhassan, Kelly, and Mulholland vested immediately, while the remainder would vest "on the date on which [CytoDyn] files its BLA for HIV combination therapy with the FDA."

254. The December 2019 awards were an egregious act of self-dealing to profit from material non-public information. Not only were these the largest awards these insiders had ever received, they were publicly rationalized as necessary to "align . . . with industry standards" and were "consistent with the Company's desire to provide compensation in line with its competitors, but the Board had never analyzed or considered the "industry standards" when it approved the awards. *Alpha Venture* Complaint, ¶¶ 107-110. Rather, they were "spring-loaded" awards granted just prior to the release of positive financial information – on December 23, 2019 (two business days following the grant), CytoDyn announced "continued promising clinical responses

from its metastatic triple-negative breast (mTNBC) Phase 1b/2 trial," causing the stock price to soar by 55% to $0.98 per share on December 27, 2019. Thus, within a matter of days of the grant, the December 2019 awards were in-the-money by $0.35 per share, or $3,255,000 in the aggregate.

255. After Klump resigned, on January 18, 2020, Pourhassan, Kelly, Naydenov, and Welch awarded themselves another 11.5 million shares in equity awards. The awards have no exercise price or trading restrictions, but using the $1.05 closing price on the date of the grant, the equity awards were valued at approximately $12 million.

256. The December 2019 and January 2020 equity awards prompted derivative litigation brought by six shareholders, including Gould and entities managed by Dockery and Caracciolo. Timmins and Patel constituted a special litigation committee ("SLC") formed to investigate and, if it determined necessary, prosecute the claims raised by the derivative complaint. Timmins and Patel had been deemed independent with respect to those claims because they were appointed to the Board after the awards were approved. The litigation culminated in a settlement pursuant to which Naydenov, Klump, and Welch forfeited their December 2019 awards in their entirety; Kelly forfeited 60% of his December 2019 award; and Pourhassan forfeited the warrant to acquire 2 million shares as well as the vested options to purchase 373,000 shares.[9] The Board was also required to institute certain governance reforms regarding compensation policies.

257. During an hearing regarding the settlement, Vice Chancellor Paul A. Fioravanti Jr. commented that he was concerned that Pourhassan was allowed to keep even a portion of the awards when there was "not even a pretense of evaluating the fairness of these grants":

> I am deeply troubled by the behavior of the defendants in approving these awards. Based upon the record, this strikes me as a case of unmitigated greed. Not only was there no process and not even a pretense of evaluating the fairness of these grants, but the leaders of this compensation decision rejected legal advice and withheld legal advice from some of the directors. . . . I am also concerned that the

[9] The January 2020 awards were forfeited because the vesting conditions were not met by the stated deadline in July 2020.

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> SLC allowed the mastermind of these awards, Mr. Pourhassan, to keep the equivalent of 40% of his awards . . . [and] the settlement does not expressly prohibit any attempt to grant replacement awards or other compensation to replace what has been forfeited in the settlement.

Despite the Delaware Chancery Court's express concern, on October 20, 2021, CytoDyn awarded Pourhassan and Kelly 4,275,000 stock options and 1,750,000 stock options, respectively.

258. The stipulation of settlement was entered on January 27, 2021, and final approval and judgment was entered by June 2021. Timmins and Patel, who had coordinated the settlement forfeiting Pourhassan's, Kelly's, and Naydenov's awards, did not stand for reelection at the annual meeting in November 2021, purportedly "for personal reasons." They were replaced by Lishomwa C. Ndhlovu and Tanya Durkee Urbach, who were "recommended by [CytoDyn's] Chairman of the Board and Chief Medical Officer," i.e. Kelly. Kelly is not independent from Pourhassan. As former directors allege, Kelly supported Pourhassan when he claimed "that investors would not 'respect' him unless the Company paid him more" and he "felt that Pourhassan should be kept happy due to the risk his sudden departure may have on [CytoDyn's] operations."

259. The foregoing demonstrates that any director who acts against Pourhassan's interests will be removed or forced out of the Company. As a result, the entire Board could not disinterestedly consider a demand.

Additional Reasons That Demand is Excused

260. Pourhassan is the Company's CEO, and therefore is not independent. As an employee, Pourhassan derives substantially all of his income from his employment with CytoDyn, thus he could not disinterestedly consider a demand for action that might require him to sue the directors that control his continued employment and/or fellow members of management with whom he works on a day-to-day basis. Moreover, as CEO and as alleged herein, Pourhassan personally issued the materially misleading statements alleged herein and is

named as a defendant in the Securities Class Action. As a result, Pourhassan would be interested in a demand regarding his own wrongdoing and demand is futile as to him.

261. Kelly is the Company's Chief Science Officer, Chief Medical Officer, and Head of Business Development, and therefore is not independent. As an employee, Kelly derives substantially all of his income from his employment with CytoDyn, thus he could not disinterestedly consider a demand for action that might require him to sue the directors that control his continued employment and/or fellow members of management with whom he works on a day-to-day basis. Moreover, during fiscal 2020, the Board determined that Kelly was not independent under NASDAQ listing rules. As a result, Kelly would be interested in a demand regarding his own wrongdoing and demand is futile as to him.

262. Naydenov and Timmins served as the members of the Audit Committee at relevant times. As such, they are responsible for the effectiveness of the Company's internal controls, the integrity of its financial statements, and its compliance with laws and regulations. In their capacities as Audit Committee members, Naydenov and Timmins reviewed and approved the disclosures regarding leronlimab, the Company's sole drug candidate. As alleged herein, Naydenov and Timmins failed to ensure the integrity of the Company's internal controls, allowing the materially misleading statements to be disseminated in CytoDyn's SEC filings and other disclosures. Thus, Naydenov and Timmins breached their fiduciary duties and are not disinterested, and demand is excused as to them.

COUNT I

(Against The Director Defendants For Breach Of Fiduciary Duty)

263. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

264. The Director Defendants owe the Company fiduciary obligations. By reason of their fiduciary relationships, the Director Defendants owed and owe the Company the highest obligation of good faith, fair dealing, loyalty, and due care.

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265. The Director Defendants violated and breached their fiduciary duties of care, loyalty, reasonable inquiry, and good faith.

266. The Director Defendants engaged in a sustained and systematic failure to properly exercise their fiduciary duties. Among other things, the Director Defendants breached their fiduciary duties of loyalty and good faith by allowing the Company to make false and misleading statements and failing to maintain an adequate system of oversight, disclosure controls and procedures, and internal controls as alleged herein. These actions could not have been a good faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

267. As a direct and proximate result of the Director Defendants' failure to perform their fiduciary obligations, the Company has sustained significant damages. As a result of the misconduct alleged herein, the Director Defendants are liable to the Company.

268. As a direct and proximate result of the Director Defendants' breach of their fiduciary duties, the Company has suffered damage, not only monetarily, but also to its corporate image and goodwill.

COUNT II

(Against The Director Defendants For Waste Of Corporate Assets)

269. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

270. The wrongful conduct alleged regarding the issuance of false and misleading statements and its failure to maintain an adequate system of oversight, disclosure controls and procedures, and internal controls was continuous, connected, and on-going throughout the Relevant Period. It resulted in continuous, connected, and ongoing harm to the Company.

271. As a result of the misconduct described above, the Director Defendants wasted corporate assets by, inter alia: (i) paying excessive compensation and bonuses to certain of its executive officers; (ii) awarding self-interested stock options to certain officers and directors;

and (iii) incurring potentially millions of dollars of legal liability and/or legal costs to defend Defendants' unlawful actions.

272. As a result of the waste of corporate assets, the Director Defendants are liable to the Company.

273. Plaintiffs, on behalf of the Company, have no adequate remedy at law.

COUNT III

(Against Defendants Pourhassan and Mulholland For Unjust Enrichment)

274. Plaintiffs incorporate by reference and re-allege each and every allegation set forth above, as though fully set forth herein.

275. By their wrongful acts and the omissions of material fact that they caused to be made, Defendants were unjustly enriched at the expense of, and to the detriment of, the Company.

276. Plaintiffs, as shareholders and representatives of the Company, seek restitution from Defendants Pourhassan and Mulholland and seek an order from this Court disgorging all profits, benefits, and other compensation, including any performance-based or valuation based compensation, obtained by Defendants Pourhassan and Mulholland due to their wrongful conduct and breach of their fiduciary duties.

277. Further, Defendants Pourhassan and Mulholland dumped millions of shares. For example, on April 30, 2020, after exercising options to purchase millions of CytoDyn shares at prices less than $1.00 per share, Defendant Pourhassan sold over 4.8 million shares of CytoDyn stock, for over $15.7 million in total proceeds. Defendant Pourhassan's sale was approximately 85% of his total holdings of CytoDyn stock. In addition, on December 21, 2020, Defendant Mulholland sold over 1.1 million shares for over $5.8 million in total proceeds. Thereafter, on December 28, 2020, Defendant Mulholland sold over 711,000 shares for over $4.4 million in total proceeds.

278. By their wrongful acts, violations of law, and false and misleading statements and omissions of material fact that they made and/or caused to be made, Defendants Pourhassan and Mulholland were unjustly enriched at the expense of, and to the detriment of, the Company.

279. Plaintiffs, on behalf of the Company, have no adequate remedy at law.

COUNT IV

(Against Defendants Pourhassan and Mulholland for Contribution for Violations of Sections 10(b) and 21D Of The Exchange Act)

280. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

281. The Company, along with Defendants Pourhassan and Mulholland are named as defendants in the Securities Class Actions, which assert claims under the federal securities laws for violations of Sections 10(b) and 20(a) of the Exchange Act, and SEC Rule 10b-5 promulgated thereunder. If and when the Company is found liable in the Securities Class Actions for these violations of law, the Company's liability will be in whole or in part due to Defendants Pourhassan and Mulholland's willful and/or reckless violations of their obligations as officers and directors of the Company.

282. Through their positions of control and authority as officers of the Company, Defendants Pourhassan and Mulholland were able to and did, directly and/or indirectly, exercise control over the business and corporate affairs of the Company, including the wrongful acts described in the Securities Class Actions and herein.

283. As such, Defendants Pourhassan and Mulholland are liable under 15 U.S.C. § 78j(b), which creates a private right of action for contribution, and Section 21D of the Exchange Act, 15 U.S.C. § 78u-4(f), which governs the application of a private right of action for contribution arising out of violations of the Exchange Act.

284. Defendants Pourhassan and Mulholland have damaged the Company and are liable to the Company for contribution.

285. No adequate remedy at law exists for Plaintiffs by and on behalf of the Company.

COUNT IV

(Against Defendants Pourhassan, Mulholland and Kelly: Insider Trading)

286. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

287. During the Relevant Period, Defendants Pourhassan, Mulholland and Kelly owed the Company duties of loyalty, good faith, and care as officers and directors of the Company.

288. By virtue of their positions as officers and directors of the Company and their exercise of control over the Company, at all times relevant to the wrongdoing complained of herein Defendants Pourhassan, Mulholland and Kelly had the power to, and did, control and influence the business and management of the Company's affairs, including its role in the facts and circumstances surrounding the wrongdoing complained of herein.

289. Defendants Pourhassan, Mulholland and Kelly breached their fiduciary duties in connection with their sales of Company stock by doing so on the basis of material, adverse, nonpublic information, to the detriment of the Company and its public stockholders.

290. Plaintiffs, on behalf of the Company have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

A. Declaring that Plaintiffs may maintain this action on behalf of the Company and that Plaintiffs are adequate representatives of the Company;

B. Finding the Director Defendants liable for breaching their fiduciary duties owed to the Company;

C. Directing Defendants to take all necessary actions to reform and improve the Company's corporate governance, risk management, and internal operating procedures to comply with applicable laws and to protect the Company and its stockholders from a repeat of the rampant wrongful conduct described herein;

D. Awarding Plaintiffs the costs and disbursements of this action, including attorneys', accountants', and experts' fees; and

E. Awarding such other and further relief as is just and equitable.

JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury of all issues so triable.

Dated: January 20, 2022

By: */s/ Duncan C. Turner*

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CERTIFICATE OF SERVICE

I hereby certify that on this 20th day of January, 2022, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to all counsel of record.

s/ Yonten Dorjee
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